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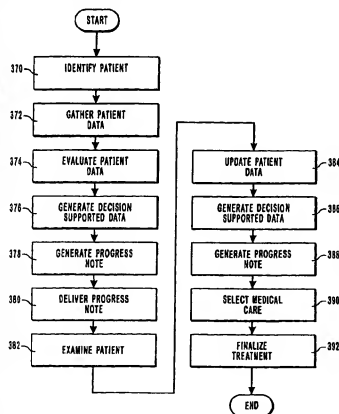
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(54) Title: SYSTEMS AND METHODS FOR MANIPULATING MEDICAL DATA VIA A DECISION SUPPORT SYSTEM



(57) Abstract: In a decision-support system having data stored in a knowledge base, a method for delivering decision-supported patient data to a clinician to aid the clinician with the diagnosis and treatment of a medical condition. The method includes gathering patient data (Fig. 11 -372) from a patient in response to a decision-supported questionnaire. The questionnaire includes a number of questions and decision-supported questions aimed at the patient and the patient's relatives. Upon gathering the patient data, the patient data is evaluated (Fig.11 -382) with the knowledge base to generate decision-supported patient data (Fig.11 -376). The decision-supported patient data includes at least one of a medical condition diagnosis of the patient and a medical care recommendation for the patient. The decision supported patient data (Fig.11 -386) is in a format that assists the clinician in treating each patient (Fig. 11 -390). Such format may be a decision-supported progress note (Fig. 11 -388).

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1 knowledge. The rapid expansion of the scientific and clinical evidence has changed the  
health care landscape so that no longer is the question how much of medical practice is  
based in evidence, but rather how much of the available evidence is applied at the front  
lines of patient care.

5 Clinicians and health care providers are acutely aware of the issues associated  
with practicing the available evidence at the front lines. Many attempts have been made  
to provide information to a clinician in a meaningful manner that supports the clinician's  
decision-making process. One current trend is to utilize artificial intelligence (AI)  
10 technologies to meet information management and decision-supporting needs. AI  
technologies or expert systems attempt to simulate the decision-support process that is  
easily accomplished by the human brain. The expert system typically includes a  
knowledge base that stores data representative of the currently available knowledge  
within a particular field of endeavor. An inference engine and associated "rules" or  
15 statements that control how the expert system reacts to a particular situations work with  
the knowledge base to generate solutions to problems posed to the expert system, such as  
the dose of a drug that a patient is to receive.

Various types of expert system have been developed in the medical field. For  
example, one type of expert system aids a physician with treating physical trauma. The  
expert system gathers patient data, such as the patient's height, weight, age, and sex,  
20 while collecting information related to the physical trauma. As the data is collected, the  
expert system generates a working file that is specific to the patient and the particular  
injury. This working file with a knowledge base of physical trauma and orthopedic  
fractures is used by the expert system to assist the clinician in treating the patient's  
physical trauma. Unfortunately, each working file is specific to the particular patient and  
25 the specific injury. Hence, each time the expert system is used, a new working file is  
generated, including the need to ask for patient data, patient history, and the like.

Another type of expert system guides a clinician with the administration and  
selection of therapeutic drugs and associated treatment regimens for a known disease.  
The expert system utilizes information gathered from a patient physical examination with  
30 a knowledge base to generate suggested treatment regimens for a known disease or  
medical condition. Although this type of expert system allows a clinician and a patient to  
generate treatment regimens together for a known disease, the expert system is limited to

only those known diseases identified by the clinician. Additionally, initial generation of patient data is time consuming and cumbersome.

Therefore, there is a need for an expert system that allows for an evaluation of a patient over an extended period without the need to re-input patient data each time a clinician examines the same patient. Additionally, there is a need for a system that effectively gathers patient data without the clinician spending a long period examining the patient and evaluates the data to identify known or unknown medical conditions.

#### SUMMARY OF THE INVENTION

As disclosed previously, clinicians are influenced by a number of complex and varied constraints as a clinician gives medical care to multiple patients each having varied medical conditions. Constraints on the time that a clinician may spend consulting with each patient limit the clinician's effectiveness in diagnosing and treating each patient. Furthermore, although clinicians educate themselves with the advances in medical care, during the rigors of performing medical care for a large number of patients such knowledge may not raise to the clinician's memory. This may result in a misdiagnosis, mistreatment, or at worst the death of the patient. In accordance with the invention as embodied and broadly described herein, systems and methods for providing clinicians with patient specific data and at least one medical diagnosis and at least one medical care recommendation that are based upon a large expert knowledge base are disclosed.

One of the modules implemented by one embodiment of the present invention is a decision-support module. The decision-support module is configured to generate decision-supported patient data that may be accessed by a user module via a network. The decision-supported patient data may optionally be contained within one or more files, records, fields or data storages termed a decision-supported progress note specific to each patient.

The decision-supported patient data represents patient specific information and data that have been evaluated by a knowledge base of expert medical knowledge, resulting in a diagnosis of a patient's medical condition and a medical care recommendation. Each decision-supported progress note, therefore, includes data representative of at least one medical condition and at least one medical care recommendation for a patient. Additionally, the decision-supported progress note provides a qualitative and quantitative analysis of the patient assessment process

1 performed by the decision-support module and the clinician and the recommended plan of  
medical care suggested by the decision-support module over a short or long time period.

Another one of the modules implemented by one embodiment of the present  
invention is a user module. The user module communicates with the decision-support  
5 module by way of a web browser to act as an interface between the decision-support  
module and the clinician. In this manner, the clinician is presented with decision-  
supported patient data (such as in the form of the decision-supported progress note)  
through the web browser that gives the clinician an efficient and effective representation  
of the current medical condition of the patient.

10 The user module, either solely or in combination with the decision-support  
module, may generate a summarized version of the decision-supported patient data to  
assist the clinician in treating each patient that the clinician is to examine. The  
summarized version presents the clinician with the pertinent medical information  
associated with the patient's previous, existing, and any anticipated medical conditions.

15 According to another aspect of the present invention, in a decision-support system  
having data stored in a knowledge base, a method for delivering decision-supported  
patient data to a clinician to aid the clinician with the diagnosis and treatment of a  
medical condition is disclosed. The method optionally includes gathering patient data  
from a patient in response to a decision-supported questionnaire. The questionnaire  
20 includes a number of questions and decision-supported questions aimed at the patient.  
Alternatively, patient data may be gathered from one or more data storage modules or  
other databases.

Upon gathering the patient data, the method provides for the patient data to be  
evaluated with expert data stored in a knowledge base to generate decision-supported  
25 patient data. The evaluating step may include collecting medical condition information  
based upon the patient data. Once the medical condition is identified, the clinical  
classification of the medical condition is collected. Subsequently, data representative of  
one or more causes of the medical condition is collected. This data may be used to  
identify the microbial susceptibilities to the medical condition if the one or more causes  
30 of the medical condition are organism specific. Alternatively, mitigating factors based on  
the one or more causes of the medical condition are collected. Consequently, the  
medical condition identified is evaluated to generate the decision-supported patient data

1 that includes at least one medical condition and at least one medical care recommendation.

Following generation of the medical condition and the medical care recommendation, the decision-supported patient data is transmitted to a user module in the form of a decision-supported progress note. The user modules present the clinician with the decision-supported patient data specific to the patient in a format that assists the clinician in treating each patient.

In this manner, the present invention is capable of receiving patient data, optionally directly from the patient and generating decision-supported patient data that assists a clinician in making decisions related to the medical care of a patient.

Similarly, by generating data on a patient's relatives, the present invention is capable of generating decision-supported data that assists a clinician in making decisions related to the medical care of a patient and furthermore in making decisions related to the medical care of one or more of the patient's relatives.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In order that the manner in which the above-recited and other advantages and features of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1 illustrates an exemplary system that provides a suitable operating environment for the present invention;

Figure 2 is a schematic representation of one embodiment of the system of the present invention;

Figure 3 is a more detailed schematic representation of the system of Figure 2;

Figure 4 is a flow diagram representing data flow through the system of Figures 2 and 3 in an outpatient setting;

Figure 5 is a flow diagram representing data flow through the system of Figures 2 and 3 in an outpatient setting where an unknown medical condition is identified;

1       Figure 6A-6E illustrate Table 1 that contains statements that may be presented to the clinician and the underlying rules used by an inference module to generate the statements for the medical condition of Pneumonia;

5       Figure 7 illustrates Table 2 that contains mitigating factor rules used by an inference module for the medical condition of Pneumonia;

      Figure 8 illustrates Table 3 that contains susceptibility rules used by an inference module for the medical condition of Pneumonia

      Figure 9 illustrates Table 4 that contains duration rules used by an inference module for the medical condition of Pneumonia

10       Figure 10 illustrates Table 5 that contains caveat rules used by an inference module for the medical condition of Pneumonia

      Figure 11 is a flow diagram representing data flow through the system of Figures 2 and 3 in an inpatient setting.

15       Figure 12A-B is a schematic block diagram illustrating the various etiologic classifications for a Urinary Tract Infection that may be presented to the clinician in accordance with the teaching of the present invention;

      Figure 13A-F illustrates Table 6 that contains statements that may be presented to the clinician and the underlying rules used by an inference module to generate the statements for the medical condition of a Urinary Tract Infection;

20       Figure 14 illustrates Table 7 that contains statements that the present invention may present to the clinician and the underlying rules used by an inference module to generate the statements for a Candida medical condition and other miscellaneous organism associated with a Urinary Tract Infection;

25       Figure 15 illustrates Table 8 that contains duration rules and statements associated with the medical condition of a Urinary Tract Infection;

      Figure 16 illustrates Table 9 that contains caveat rules and statements associated with the medical condition of a Urinary Tract Infection;

      Figure 17 illustrates Table 10 that contains mitigating factor rules and statements associated with the medical condition of a Urinary Tract Infection;

30       Figure 18 illustrates Table 11 that contains sequential mitigating factor rules and statements associated with the medical condition of a Urinary Tract Infection;

1           Figure 19 illustrates Table 12 that contains illustrative medication contraindications for the medical condition of a Urinary Tract Infection;

          Figure 20A-B is a schematic representation of the decision-support process for a medical condition of meningitis;

5           Figure 21A-C illustrates Table 13 that contains statements that the present invention may presented to the clinician and the underlying rules used by an inference module to generate the statements for the medical condition of Meningitis;

          Figure 22 illustrates Table 14 that contains duration rules associated with the medical condition of Meningitis;

10          Figure 23 illustrates Table 15 that contains mitigating factor rules associated with the medical condition of Meningitis; and

          Figure 24 illustrates Table 16 that contains caveat rules associated with the medical condition of Meningitis.

#### **DETAILED DESCRIPTION OF THE INVENTION**

15          The present invention extends to both methods and systems for delivering decision-supported patient data to a clinician to aid the clinician with the diagnosis and treatment of a medical condition. The embodiments of the present invention may comprise a special purpose or general purpose computer including various other computer hardware and/or software modules and components, as discussed in greater detail below.

20          Embodiments within the scope of the present invention also include computer-readable media for carrying or having computer-executable instructions or data structures stored thereon. Such computer-readable media can be any available media that can be accessed by a general purpose or special purpose computer. By way of example, and not limitation, such computer-readable media can comprise RAM, ROM, EEPROM, CD-ROM or other optical disk storage, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to carry or store desired program code means in the form of computer-executable instructions or data structures and which can be accessed by a general purpose or special purpose computer. When information is transferred or provided over a network or another communications connection (either  
25          hardwired, wireless, or a combination of hardwired or wireless) to a computer, the computer properly views the connection as a computer-readable medium. Thus, any such  
30          a connection is properly termed a computer-readable medium. Combinations of the

1 above should also be included within the scope of computer-readable media. Computer-executable instructions comprise, for example, instructions and data which cause a general purpose computer, special purpose computer, or special purpose processing device to perform a certain function or group of functions.

5 Figure 1 and the following discussion are intended to provide a brief, general description of a suitable computing environment in which the invention may be implemented. Although not required, the invention will be described in the general context of computer-executable instructions, such as program modules, being executed by computers in network environments. Generally, program modules include routines, programs, objects, components, data structures, etc. that perform particular tasks or implement particular abstract data types. Computer-executable instructions, associated data structures, and program modules represent examples of the program code means for executing steps of the methods disclosed herein. The particular sequence of such executable instructions or associated data structures represents examples of corresponding acts for implementing the functions described in such steps.

15 Those skilled in the art will appreciate that the invention may be practiced in network computing environments with many types of computer system configurations, including personal computers, hand-held devices, multi-processor systems, microprocessor-based or programmable consumer electronics, network PCs, minicomputers, mainframe computers, and the like. The invention may also be practiced in distributed computing environments where tasks are performed by local and remote processing devices that are linked (either by hardwired links, wireless links, or by a combination of hardwired or wireless links) through a communications network. In a distributed computing environment, program modules may be located in both local and remote memory storage devices.

20 With reference to Figure 1, an exemplary system for implementing the invention includes a general purpose computing device in the form of a conventional computer 20, including a processing unit 21, a system memory 22, and a system bus 23 that couples various system components including the system memory 22 to the processing unit 21. The system bus 23 may be any of several types of bus structures including a memory bus or memory controller, a peripheral bus, and a local bus using any of a variety of bus architectures. The system memory includes read only memory (ROM) 24 and random

1 access memory (RAM) 25. A basic input/output system (BIOS) 26, containing the basic routines that help transfer information between elements within the computer 20, such as during start-up, may be stored in ROM 24.

5 The computer 20 may also include a magnetic hard disk drive 27 for reading from and writing to a magnetic hard disk 39, a magnetic disk drive 28 for reading from or writing to a removable magnetic disk 29, and an optical disk drive 30 for reading from or writing to removable optical disk 31 such as a CD-ROM or other optical media. The magnetic hard disk drive 27, magnetic disk drive 28, and optical disk drive 30 are connected to the system bus 23 by a hard disk drive interface 32, a magnetic disk drive-  
10 interface 33, and an optical drive interface 34, respectively. The drives and their associated computer-readable media provide nonvolatile storage of computer-executable instructions, data structures, program modules and other data for the computer 20. Although the exemplary environment described herein employs a magnetic hard disk 39, a removable magnetic disk 29 and a removable optical disk 31, other types of computer  
15 readable media for storing data can be used, including magnetic cassettes, flash memory cards, digital video disks, Bernoulli cartridges, RAMs, ROMs, and the like.

Program code means comprising one or more program modules may be stored on the hard disk 39, magnetic disk 29, optical disk 31, ROM 24 or RAM 25, including an  
20 operating system 35, one or more application programs 36, other program modules 37, and program data 38. A user may enter commands and information into the computer 20 through keyboard 40, pointing device 42, or other input devices (not shown), such as a microphone, joy stick, game pad, satellite dish, scanner, or the like. These and other input devices are often connected to the processing unit 21 through a serial port interface  
25 46 coupled to system bus 23. Alternatively, the input devices may be connected by other interfaces, such as a parallel port, a game port or a universal serial bus (USB). A monitor 47 or another display device is also connected to system bus 23 via an interface, such as video adapter 48. In addition to the monitor, personal computers typically include other peripheral output devices (not shown), such as speakers and printers.

30 The computer 20 may operate in a networked environment using logical connections to one or more remote computers, such as remote computers 49a and 49b. Remote computers 49a and 49b may each be another personal computer, a server, a router, a network PC, a peer device or other common network node, and typically

1 includes many or all of the elements described above relative to the computer 20,  
although only memory storage devices 50a and 50b and their associated application  
programs 36a and 36b have been illustrated in Figure 1. The logical connections depicted  
in Figure 1 include a local area network (LAN) 51 and a wide area network (WAN) 52  
5 that are presented here by way of example and not limitation. Such networking  
environments are commonplace in office-wide or enterprise-wide computer networks,  
intranets and the Internet.

When used in a LAN networking environment, the computer 20 is connected to  
the local network 51 through a network interface or adapter 53. When used in a WAN  
10 networking environment, the computer 20 may include a modem 54, a wireless link, or  
other means for establishing communications over the wide area network 52, such as the  
Internet. The modem 54, which may be internal or external, is connected to the system  
bus 23 via the serial port interface 46. In a networked environment, program modules  
depicted relative to the computer 20, or portions thereof, may be stored in the remote  
15 memory storage device. It will be appreciated that the network connections shown are  
exemplary and other means of establishing communications over wide area network 52  
may be used.

Figure 2 is a block diagram illustrating a decision support system implementing  
one embodiment of the present invention. As shown, system 200 includes a decision-  
20 support module 210 that communicates with one or more user modules 214a-214n via  
network 212. Alternatively, system 200 may include multiple decision-support modules  
that communicate with a single user module. Through the configuration illustrated in  
Figure 2, a patient or clinician may input information regarding the patient's health,  
medical conditions, billing information, and past and current medical care, termed  
25 "patient data". Subsequently, system 200 may evaluate this patient data to create data  
that assists the clinician in making a medical diagnosis, a medical care recommendation  
or decision, medical treatment, a referral to another clinician or medical provider, or the  
like. Such data is termed "decision-supported patient data."

30 Optionally, the decision-supported patient data may be configured in the form of a  
decision-supported progress note. The decision-supported progress note is a module, data  
file, record, field, one or more data storages that contain information and data that  
represents a qualitative and quantitative analysis of the patient assessment process

1 performed by the decision-support module 210 and the clinician and the recommended plan of medical care suggested by decision-support module 210. Such qualitative and quantitative analysis may extend over a long period, such as with an outpatient situation, or over a shorter period, such as with an inpatient situation.

5 In this manner, system 200 may gather and analyze stored patient data with input patient data to generate decision-supported patient data, optionally, in real-time or perceived real time. Although discussion is made to the use of the present invention in a decision-support system, it may be appreciated that the novel features of the present invention are not limited to use with a decision-support system, but may be used in  
10 various other systems:

As illustrated in Figure 2, system 200 includes decision-support module 210. Decision-support system 210, in one embodiment, allows a patient to store and access patient data, while allowing a clinician to store, update, and access the patient data and decision-supported patient data that contain information regarding the diagnosis and  
15 treatment of various medical conditions. Additionally, the clinician may access a knowledge base that includes data representative of the current expert medical knowledge within a variety of medial areas and assists the clinician with the diagnosis and medical care of the patient. The patient data, the decision-supported patient data, and the knowledge base need not be incorporated within decision-support module 210, but may  
20 be located remotely from decision-support module 210 and accessible by decision-support module 210. For example, optional medical module 216, as illustrated by dotted lines, may include one or more servers that store the patient data, the decision-supported patient data, and the knowledge base.

Facilitating communication between decision-support module 210, user modules  
25 214a-214n, and optionally medical module 216 is network 212. In one embodiment, network 212 is the Internet so that various user modules 214a-214n using web browsers may access the patient data, decision-supported patient data, and decision-supported progress notes stored within decision-support module 210. Network 212 may also be a local area network (LAN) such as a hospital or clinic intranet, wide area network (WAN),  
30 wireless network, packetized network, real-time network, and various other networks known by one skilled in the art, so long as the network configuration and architecture allow a user module to access decision-support module 210.

1 Decision-support module 210 may communicate with user modules 214a-214n via  
various types of communication line connections, such as but not limited to, cable or  
cable modems, satellite, telephone lines, whether analog or digitally based, the Internet,  
DSL, G-Lite, wireless technology, infra-red (IR) technology, other high-speed data  
5 connections, or any other suitable transmission technology or medium. One skilled in  
the art may identify various other types of network and/or communication line  
connections that are capable of performing the desired function of allowing decision-  
support module 210 to communicate with user modules 214a-214n and optionally  
medical module 216.

10 Each user module 214a-214n communicates with decision-support module 210 to  
allow the clinician or patient to gather patient data and receive decision-supported patient  
data or the decision-supported progress note in real-time or perceived real-time. As  
discussed herein, the operation of either transmitting data and/or receiving data, in various  
forms and types, shall be termed collectively as "transceiving" and the operation of  
15 tranceiveing data between decision-support module 210, user module 214a-214n, and  
medical module 216 without a substantial delay between an input and a response is  
considered real-time or perceived real-time communication.

Those skilled in the art will appreciate that each user module 214a-214n may take  
various configurations. For example, each user module 214a-214n may be the same or  
20 different personal computer, hand-held device, multi-processor system, microprocessor-  
based or programmable consumer electronic device, telephone, network PC,  
minicomputer, mainframe computer, and the like. Generally, each user module 214a-  
214n may include the structure and functionality of computer 20 with associated  
application programs 36 and memory 22 to store the application programs 36, patient  
25 data, decision-supported patient data, and optional decision-supported progress note.

Medical module 216 represents the various hardware and software modules and  
components of a medical facility, such as a hospital, clinic, and the like. Each medical  
facility may store business data, medical data, patient data, decision-supported patient  
data, decision-supported progress notes, and the like. Medical module 216, in one  
30 embodiment, includes various modules associated with the medical facility's intranet or  
internal network that links various departments of a hospital or clinic. For example, the  
departments may include radiology, the pharmacy, administration, the laboratories, and

1 the like. Additionally, medical module 216 may include the hardware and software modules and components for medical module 216 to communicate with decision-support module 210 and user modules 214a-214n by a communication line connection known to one skilled in the art in light of the teaching contained herein.

5 According to another aspect of the present invention, system 200 optionally includes a third party module 218. Third party module 218 represents the various other modules that may communicate with decision-support module 210, user modules 214a-214n, and medical module 216. For example, third party module 218 may represent a medical provider, an insurance carrier, a referred clinician, a referring clinician, a third party paging service, and the like. In this manner, a clinician may communicate with 10 outside sources to obtain approval for services and/or give information to the outside sources. For example, system 200 may allow decision-support module 210 to communicate with an insurance carrier, health care management organization (HMO), or other similar health care provider to receive authority to give a recommended medical treatment. One skilled in the art may identify various other third parties that may obtain 15 benefits from the present invention.

Generally, the configuration of system 200 facilitates the gathering of patient data and delivery of decision-supported patient data to a clinician and patient. Optionally, system 200 may present the clinician or patient with a summarized version of the 20 available medical and non-medical information via user module 214a-214n. Such medical and non-medical information provides the clinician and the patient with recommendations regarding the patient's care and may include warnings or alerts with respect to recommended treatments or potential medical conditions of the patient. For example, the alerts may identify potential side effects associated with the use of the 25 medication.

By summarizing the decision-support patient data, the clinician is not bombarded with a large quantity of information through which he or she must search. Rather, the clinician may view the current decision-supported patient data, i.e., recent laboratory test results, vital statistics, current drug usage, and the like. In this fashion, the clinician is 30 given a simplified representation of the patient's medical condition based upon the current medical knowledge and the current patient data. Thus, medical costs are reduced and a higher quality of medical care is provided to each patient.

1 Furthermore, the configuration of system 200 facilitates the delivery of patient  
data to the clinician in a standardized and reproducible manner. The clinician may request  
real-time patient data from decision-support module 210, medical module 216, or third-  
party module 218 on demand and receive the patient data in a standardized format. Such  
5 patient data may be delivered to the clinician via user module 214a-214n and displayed to  
the clinician through a browser or other user interface. Additionally, the configuration of  
system 200 facilitates the delivery of important or critical information and patient data to  
the clinician, whether in a synchronized basis or upon the occurrence of an alerted event,  
such as when a patient has heart attack or an adverse reaction to prescribed medication.

10 Generally, each of the modules, 210, 214a-214n, 216, and 218 may be  
incorporated within various types of computer 20 and remote computers 49a, 49b as  
depicted in Figure 1. Each module 210, 214a-214n, 216, and 218, therefore, may include  
system memory 22 and storage devices 50a and 50b, while optionally including hard disk  
15 drive 27, magnetic disk drive 28, optical disk drive 30, and associated interfaces 32, 33,  
and 34. Additionally, each module 210, 214a-214n, 216, and 218 may communicate one  
with another via a variety of different manners and communication line connections.  
Hence, the functionality of each module 210, 214a-214n, 216, and 218 may be  
incorporated within one or more of the other modules. For example, the functionality of  
20 decision-support module 210 and/or of user modules 214a-214n may be incorporated  
within medical module 216.

With reference to the more detailed schematic representation of one embodiment  
of the present invention depicted in Figure 3, only a single decision-support module 210  
and a single user module 214 are depicted. The following discussion will relate to the  
interaction between one decision-support module 210 and one user module 214. One  
25 skilled in the art may appreciate, however, that a similar discussion may be recited for the  
interaction of multiple decision-support modules and multiple user modules.

According to one embodiment of the present invention decision-support module  
210 includes a patient storage module 220. Patient storage module 220 stores the patient  
data that may be used by the clinician and decision-support module 210 to establish the  
30 type of medical care received by the patient. As illustrated, patient storage module 220  
includes one or more databases 222a-222n that maintain the patient data. Each database  
222a-222n may have various architectures, such as but not limited to, relational, network,

1 flat, and hierarchical databases, with associated database management systems (not  
shown) that control the flow of data to and from databases 222a-222n. Although multiple  
databases are represented, one skilled in the art may appreciate that system 200 may  
include only a single database.

5 The patient data maintained in databases 222a-222n may include, but is not  
limited to, the patient's billing information (e.g., name, address, telephone number, birth  
data, social security number; and insurance information) and patient's demographic  
information (e.g., age, sex, height, and weight). Additionally, databases 222a-222n  
include the patient's past and current: (i) medical conditions; (ii) medical care; (iii)  
10 tracked cure and failure information; (iv) medications prescribed and associated adverse  
effects of drug interactions; (v) laboratory tests and results; (vi) clinical consequences of  
treatment; (vii) family histories; (viii) genetic susceptibilities and pharmacological and  
non-pharmacological information; (ix) decision-supported patient data and progress  
notes; (x) and the like. Such data may be stored in a variety of different fields, files, and  
15 records that are associated one with another to allow an appropriate database management  
system (not shown) to access the stored data in an efficient manner when requested by  
interface module 230.

In accordance with another aspect of the present invention, decision-support  
module 210 includes a knowledge module 226. Knowledge module 226, and associated  
20 databases 228a-228n, act as the repository of medical information, data, and associated  
rules and parameter descriptions i.e., "knowledge", which decision-support module 210  
uses to identify an unknown medical condition of a patient or provide recommendations  
for treatment of the medical condition when the condition is known or unknown. The  
rules represent logic sectors or elements that act upon information gathered by system  
25 200 to generate the decision-supported patient data and the decision-supported progress  
note. The rules are either sequential or non-sequentially followed to generate the medical  
care recommendations. Following hereinafter are a list of illustrative rules that system  
200 may use to generate the decision-supported patient data and decision-supported  
progress note based upon stored and newly gathered patient data and/or patient data  
30 associated with the patient's relatives.

The medical information and data stored within knowledge module 226 are based  
on information from experts within the relevant fields of medicine, such as such as

Geriatric Medicine, Genetic Medicine and Gene Therapy, Cardiovascular diseases, Respiratory diseases, and the like. Knowledge module 226, therefore, may include information related to, but not limited to, Critical Care Medicine, Renal diseases, Genitourinary diseases, Gastrointestinal diseases, Diseases of the liver, gallbladder, and bile ducts, Hematologic diseases, Oncology, Metabolic diseases, Nutritional diseases, Endocrine diseases, Women's Health, Diseases of bone and bone mineral metabolism, Diseases of the immune system, Musculoskeletal and connective tissue diseases, Infectious diseases, HIV and Acquired immunodeficiency syndrome, Diseases of protozoa and metazoa, Neurological Diseases, Eye, Ear, Nose, and Throat diseases, Skin diseases, Pediatric Medicine, and the like.

The rules and parameter descriptions stored in knowledge module 226 may include one or more software modules, files, and records that define how decision-support module 210 uses the expert information to analyze the patient's current medical information. In this manner, the clinician is guided with the identification and treatment of a patient's medical condition. Such rules and parameters are dynamic in that as system 200 gathers more "knowledge" the rules and parameters changes to accommodate the increased knowledge. This is in contrast to many existing expert systems that utilize hard coded rules and parameters that are difficult to vary based upon an increasing knowledge base. Illustrative rules and parameters related to Pneumonia, Meningitis, and Urinary tract Infection will be discussed hereinafter.

As with databases 222a-222n, each database 228a-228n may have various architectures, such as but not limited to, relational, network, flat, and hierarchical databases, with associated database management systems (not shown) that control the flow of data to and from databases 228a-228n. It may be appreciated that is preferable that databases 222a-222n and 228a-228n have the same architecture, however, each database 222a-222n and 228a-228n may have differing architectures.

Although Figure 3 illustrates each database 222a-222n and 228a-228n as being incorporated within decision-support module 210, one skilled in the art may appreciate that such databases 222a-222n and 228a-228n and/or patient storage module 220 and knowledge module 226 may be remotely located from decision-support module 210. Alternatively, in one configuration, patient storage module 220 and/or databases 222a-222n may be incorporated within a hospital or clinic's administrative system and/or

1 network (medical module 216) that allow decision-support module 210 to access the  
information stored therein. In another configuration, patient storage module 220 and/or  
databases 222a-222n are located remotely from decision-support module 210 and a  
hospital or clinic's administrative system and/or network (medical module 216).

5 Communicating with patient storage module 220 and/or knowledge module 226 is  
an interface module 230. Interface module 230 facilitates the decision-support process by  
providing access to databases 222a-222n and 228a-228n. Interface module 230,  
therefore, allows decision-support module 210 to obtain patient data from medical  
10 module 216. Such communication between interface module 230 and medical module  
216 may be via a variety of communication protocols and communication line  
connections. In one illustrative embodiment, interface module 230 allows  
communication via the Health Level 7 protocol, via Extensible Markup Language  
(XML), or by some other communication protocol known by one skilled in the art in light  
15 of the teaching contained herein. As may be understood by one skilled in the art,  
interface module 230 may be generated by a variety of different software tool and  
products, such as but not limited to Enterprise Java Beans (EJB), Common Object  
Request Broker Architecture (COBRA), and Common Object Model (COM) compliant  
services, and the like.

20 Communicating with interface module 230 is inference module 232. Inference  
module 232 controls the manner by which decision-support module 210 generates  
solutions to the known or unknown medical conditions of the patient. Stated another  
way, inference module 232 generates the decision-supported patient data based upon the  
newly gathered patient data, stored patient data within patient module 220, and the  
knowledge base contained within knowledge module 226. For example, inference  
25 module 232 may use the genetic susceptibilities of the patient to identify the various  
medical conditions that the patient may be susceptible to in the future and prescribe  
medical care recommendations to reduce the likelihood of such medical conditions  
occurring.

30 Inference module 232, in one embodiment, includes one or more inference  
engines 233 and an application module 235 to drive the one or more inference engines  
233. The one or more inference engines 233 apply the rules and parameters stored in  
knowledge module 226 to generate the medical diagnosis and the medical care

1 recommendation for the patient. Application module 235, in one embodiment, includes  
the software modules to cause inference engine 233 to generate such medical diagnosis  
and medical care recommendations. The functionality and operation of these elements  
are commonly known by one skilled in the art and need not be discussed further herein.  
5 A variety of other modules and components may be included within inference module  
232 as known by one skilled in the art in light of the teaching contained herein.

As illustrated, inference module 232 is depicted as being incorporated within  
decision-support module 210. One skilled in the art may appreciate that inference module  
232 may optionally be integrated with medical module 216 by connecting decision-  
10 support module 210 directly to medical module 216 by an Internet Inter-Object Request  
Broker Protocol (IIOP) or remotely by a Remote Method Invocation (RMI).  
Alternatively, inference module 232 may be incorporated partially or completely within  
medical module 216 and hence decision-support module 210 is devoid of inference  
module 232. Additionally, inference module 232 may be incorporated within an  
15 application server hosted by decision-support module 210 or may be incorporated within  
an application server hosted by medical module 216.

Decision-support module 210, in one embodiment, includes an optional progress  
note module 236. Progress note module 236 communicates with inference module 232 to  
20 receive the decision-supported patient data and subsequently generate a decision-  
supported progress note. The decision-supported progress note presents the clinician with  
the decision-supported patient data in a standardized and reproducible configuration so  
that system 200 minimizes the potential for misdiagnosis of a medical condition or  
recommended medical treatment based upon the illegibility of a clinician's notes.  
Furthermore, the decision-supported progress note provides a clinician with a  
25 standardized format for collecting additional patient data and a list of recommended  
follow-up questions, tests, and other medical care to perform during a physical exam or  
visit with the patient. Optionally, the clinician may modify the particular configuration of  
the progress note so that the clinician may more effectively give medical care to a patient.  
Consequently, progress note module 236 may allow a clinician to define how the  
30 decision-supported patient data is to be displayed in the decision-supported progress note.

In one setting, a clinician may request that progress note module 236 summarize  
the decision-supported patient data generated by inference module 232. The summarized

1 decision-supported patient data contains the pertinent information related to the medical  
condition of the patient in an easily viewed display. For example, if the patient has  
diabetes, progress note module 236 will generate a decision-supported progress note that  
summarizes the pertinent medical parameters associated with the patient's diabetes, such  
5 as the most recently acquired heart rate, blood pressure, blood sugar level, and the like,  
while providing warnings or alerts to the clinician. Similarly, when a therapeutic regimen  
is suggested, progress note module 236 summarizes decision-supported patient data  
includes drug name and type, dose, route, interval and duration of therapy specific to the  
patient and the drug, patient demographics, and the like, while providing warnings or  
10 alerts to the clinician.

In this manner, progress note module 236 may provide the clinician with the  
pertinent patient specific decision-supported patient data in a summarized arrangement  
requested by the clinician. By summarizing the pertinent data, a clinician more capably  
treats a patient in an efficient manner.

15 In another configuration, progress note module 236 generates a decision-  
supported progress note that includes a calendar representing when a patient is to take  
medication that is prescribed by the clinician. Optionally, the calendar includes a visual  
representation of the medication prescribed. For example, if the clinician prescribes  
1000mg of ganciclovir then the calendar may include a visual representation of two (2)  
20 500mg pills containing ganciclovir. In this manner, the calendar both reminds the patient  
when to take their medication, while also giving a visual representation of the number of  
the pills prescribed.

To allow inference module 232 and/or progress note module 236 to transceive  
information to and from user module 214, decision-support module 210 optionally  
25 includes a web module 238. Web module 238, in one embodiment may be a web server  
that facilitates data transceiving between decision-support module 210 and user module  
214. Web module 238, either alone or in combination with inference module 232 and/or  
progress note module 236 may control how and when the decision-supported patient data  
is presented to the clinician and/or patient. For example, in one embodiment, web  
30 module 238 provides the decision-supported patient data by way of a web page that is  
accessible by clinicians and/or patients via user module 214. Therefore, web module 238  
defines the layout or format of the web page. Optionally, the clinician and/or the patient

1 may vary the particular configuration of the web page upon which they will view the  
decision-supported patient data.

One skilled in the art may identify various other configurations of web module  
238 that are applicable. For example, in one configuration, web module 238  
5 automatically delivers patient data to the clinician as the clinician accesses web module  
238, such as broadcasting updated patient data. In still another configuration, such as  
with an inpatient setting, web module 238 continually or periodically updates the  
decision-supported patient data or decision-supported progress noted and subsequently  
transmits (or broadcasts) warning or alerts to the clinician based upon the updated patient  
10 data. For instance, upon completing laboratory tests a laboratory clinician may broadcast  
the updated laboratory results to decision-support module 210 by way of laboratory  
module 262. Subsequently, web module 238 updates decision-support patient data and  
decision-supported progress notes and delivers a notification or warning to the clinician's  
user module, such as a pager, telephone, PDA, a clinician's assistant that may forward the  
15 notification or warning, some third party service provider or the like. In another  
configuration, web module 238 delivers patient data, decision-supported patient data,  
and/or decision supported progress note to third party module 218. For example, if  
decision-support module 210 identifies that as a medical care recommendation the patient  
may be referred to a specialist, upon authorization by the clinician, web module 238  
20 delivers a decision-supported progress note to the clinician with a referral request to an  
identified clinician or to an insurance carrier or other medical provider. Subsequently,  
upon authorization from the clinician, web module 238 may send the referral request  
directly to an identified clinician or to an insurance carrier or other medical provider. In  
another configuration, web module 238 allows a patient or clinician to request additional  
25 information via electronic mail (e-mail) or by some other manner from a group of  
specialists. For example, a clinician may identify that a patient has contracted  
tuberculosis and request guidance from a medical care specialty group (such as third party  
218) on what actions to take in light of the medical condition. In response, the specialty  
group or a clinician part thereof may response the to clinician's request via e-mail or  
30 some other manner, such as telephone, video-conference, and the like.

Web module 238 may transceive information and data via Hypertext Transfer  
Protocol (HTTP), File Transfer Protocol (FTP), Wireless Application Protocol (WAP), or

1 various other communication protocols and communication line connections. One skilled  
in the art may identify various other communication protocols and connections that are  
applicable for allowing web module 238 to transceive data between user module 214 and  
5 medical module 216. For example, web module 238 may use TCP/IP communication  
protocol, a connection orientated or connectionless network protocol, via asynchronous  
transfer mode (ATM) technology, X.25 protocol, Frame Relay protocol, packet switching  
protocols, circuit switching protocols, dynamic packet switching protocols, 802.11RF  
10 protocol, and the like to transceive data through network 212. Therefore, web module  
238 and hence decision-support module 210 may use a variety of different interface types,  
such as but not limited to a wireless interface thereby utilizing IR, RF, satellite, blue tooth  
transmission and associated protocols, a modem, cable modem, ADSL connection, ISDN,  
Ethernet, or similar other connections, and the like.

One skilled in the art may appreciate that inclusion of web module 238 within  
decision-support module 210 is optional. In the event that decision-support module 210  
15 is partially or completely incorporated within medical module 216, decision-support  
module 210 is devoid of web module 238 and may utilize an appropriate web module  
incorporated within medical module 216 to allow communication with user module 214  
via network 212.

Optionally included within decision-support module 210 is a billing module 240.  
20 Billing module 240 is configured to communicate with web module 238 and generate the  
appropriate billing codes and proper documentations required to allow accurate billing of  
medical care to insurance carriers, government agencies, Medicare, and the like. Once a  
clinician has completed a patient examination, web module 238 receives the clinician's  
25 authorization for the medical care proscribed. Subsequently, billing module 240 tracks  
the medical care authorized by the clinician for each patient and creates the billing codes  
and documentation for each procedure, drug prescribed, test requested, and the like.  
Although billing module 240 is depicted as being incorporated within decision-support  
module 210, one skilled in the art may recognize that billing module 240 may be take the  
30 form of a stand-alone module. Alternatively, billing module 240 may be incorporated  
within medical module 216. Optionally, billing module 240 may communicate with  
medical module 216 and generate the billing codes and documentation through the  
medical facilities accounting, administration, or other facilities.

Referring again to Figure 3, communicating with decision-support module 212 is user module 214. User module 214 allows a clinician and/or patient to gather patient data and subsequently receive real-time or perceived real-time decision-supported patient data or decision-supported progress notes. User module 214, as mentioned above, may take the form of computer 20 and/or remote computer 49a and 49b that allows a clinician and/or patient to gather and view medical information and associated medical diagnoses and treatments. Illustratively, user module 214 may be a personal digital assistant (PDA) or other hand-held hardware device, including, but not limited to, a Palm Pilot, or CE based palm computer, with associated software applications and operating systems, a general purpose computer, a special purpose computer, a pager, a wireless telephone, pocket PC, and the like. Additionally, such user modules 214 may synchronize or communicate with decision-support module 212 to transceive patient data, decision-supported patient data, and decision-supported progress notes on a continuous, substantially continuous, periodic, and/or sporadic manner. Such synchronization or communication may be achieved through wireless, direct dial, desktop or some other synchronization and by one of a variety of communication line connections as discussed herein and known to one skilled in the art.

User module 214, in one embodiment, includes a communication interface 242, a control module 244, and a user interface 246. Communication interface 242 of user module 214 is adapted to transceive data between decision-support module 210, medical module 216, and user module 214. Depending on the type of communication line connection between modules 210, 214, and 216, communication interface 242 may have a variety of configurations and perform a number of functions. For example, communication interface 242 may be a wireless interface thereby utilizing IR, RF, satellite, blue tooth transmission and associated protocols, a modem, cable modem, ADSL connection, ISDN, Ethernet, or similar other connections and other communication line connections known to one skilled in the art in light of the teaching contained herein. Additionally, communication interface 242 may compress, decompress, encrypt, decrypt, and perform such other functions as known by one skilled in the art.

As implied above, communication interface 242 communicates with control module 244. Control module 244 performs a number of operations and functions to allow a clinician and/or patient to gather patient data through user interface 246. Additionally,

1 control module 244 manages the flow of decision-supported patient data and decision-  
supported progress notes to user interface 246. Control module 244, therefore, optionally  
manages the flow of patient data: (i) to and from the clinician and patient; (ii) from data  
storage module 248 to user interface 246; (iii) between user module 214 and decision-  
5 support module 210; and (iv) from medical module 216 to user module 214.

In addition to controlling the flow of patient data between the various modules  
and components of system 200, control module 244 may control the configuration of user  
interface 246. Stated another way, control module 244, in one embodiment, may receive  
display instructions from the clinician regarding how the decision-supported patient data  
10 and decision-supported progress note received from decision-support module 210 is to be  
displayed or arranged. Control module 244 may deliver such instructions to web module  
238 or progress note module 236 for such modules to prepare the decision-supported  
patient data in accordance with the clinician's instructions. Alternatively, control module  
244 may either receive the decision-supported patient data (or the decision-supported  
15 progress note) and convert the data into a form consistent with the clinician's instructions  
or function with inference module 232, progress note module 236, and web module 238  
to generate the desired display.

In the later case, control module 244 may: (i) receive through communication  
interface 242 the decision-supported patient data or the decision-supported progress note;  
20 (ii) store the decision-supported patient data or the decision-supported progress note in  
data storage module 248, decision-support module 210, medical module 216, and/or  
third-party module 218; (iii) summarize the decision-supported patient data (or decision-  
supported progress note) in accordance with the clinician's instructions to display the  
pertinent information to the clinician; and (iv) display the summarized decision-supported  
25 patient data (or decision-supported progress note) to the clinician through user interface  
246.

Optionally, control module 244 may vary the display configuration requested  
based upon the particular hardware device and software modules that will present the  
decision-supported patient data or decision-supported progress note. For example, the  
30 limitations on allowable display configurations is greater for a PDA or "thin" client than  
for a general purpose computer; hence control module 244 may limit or eliminate the

1 allowable choices or merely display the decision-supported patient data in a form applicable for the particular hardware device no matter the clinician's instructions.

In addition to controlling the manner by which the decision-supported patient data is to be displayed to the clinician, control module 244 may allow the clinician and/or patient to access detailed patient data or decision-supported patient data stored in decision-support module 210 or medical module 216. Alternatively, control module 244 may display the decision-supported patient data, without summarizing the information associated with the decision-supported patient data.

Control module 244 may include various hardware and/or software modules to perform the above-referenced functions, such as but not limited to one or more micro-controllers, central processing units, state machines, programmable logic arrays, network logical arrays, or gates, ASIC processors, software-based controllers, combination logic, combinations thereof, and a variety of other controllers known by one skilled in the art. Control module 244 may communicate with communication interface 242, user interface 246, and data storage module 248 by a variety of connections, such as but not limited to electrical communication, an analog or digital, wireless, optical, or various other types of connection by way of one of a variety of communication line connections known by one skilled in the art.

As referenced above, a clinician or patient may update the patient data, the decision-supported patient data, and the decision-supported progress note through user interface 246. Similarly, the clinician or patient may receive a graphical representation of all or a summarized version of the available the patient data, the decision-supported patient data, and the decision-supported progress note through the same user interface 246. Optionally, a clinician may control the amount of patient data, whether decision-supported or not that the patient may view-through user interface 246.

User interface 246, either alone or in combination with control module 244 and decision-support module 210, may allow a clinician or patient to define the display format of the decision-supported patient data and other patient data transmitted to user module 214 from decision-support module 210 and/or medical module 216. A clinician may, in one embodiment, select from a number of stored display configurations, use the default display configuration, or generate a clinician specific display configuration. No matter the particular display configuration selected by the clinician, the particular display

1 configuration assists a clinician in diagnosing, treating, and providing medical care to the patient.

5 In one embodiment, user interface 246 is a web browser. One skilled in the art may identify various other interfaces that are capable of performing the desired function of allowing a clinician and/or patient to gather and subsequently view medical information. For example, user interface 246 may be a graphical user interface (GUI), textual, interactive, drop-down menu, voice activated, and the like interface. User interface 246 may allow a user to select choices through pushing buttons, selecting icons, scanning bar codes, vocalization of procedure codes or medical treatments, or through 10 some other method, system, hardware device, and/or software application known to one skilled in the art. The above described interfaces may be developed from a variety of software packages such as HTML, dynamic HTML (DHTML) (including JavaScript, Cascading Style Sheets, Common Gateway Interface (CGI) scripts, cookies, Java, ActiveX, Server-Side Includes (SSI), and the like.

15 According to another aspect of the present invention, system 200 includes medical module 216. As depicted in Figure 3, medical module 216 optionally includes a web module 252 that communicates with network 212. Web module 252, such as a web server, delivers the information stored in medical module 216 over network 212 to those hardware and/or software modules that access web module 252 and have appropriate 20 access rights. Upon receiving a request from a hardware and/or software module, such as user module 214 or decision-support module 210, web module 252 provides the requested documents or information in an appropriate language, such as Hyper Text Markup Language (HTML), XML, or some other language. Web module 252 may provide the requested information via Secured Socket Layers (SSL) protocol, a Virtual Private 25 Network (VPN), asymmetric or symmetric encryption, or some other security protocol or process known to one skilled in the art. One skilled in the art may also recognize that although a single server is depicted as part of medical module 216, medical module 216 may include a plurality of web modules 252.

30 Communicating with web module 252 is an application module 254, such as an application server. Application module 254 provides the conduit between the information stored in medical module 216 and any requests for such information through web module 252. Application module 254 acts as an intermediary between the information or data

1 storage of medical module 216 and the hardware and/or software modules that request  
access to the desired information. In the illustrated configuration of Figure 3, such  
information from the ancillary module 256 may pass through application module 254  
upon a request through web module 252 to access the medical information stored in the  
5 ancillary module 256. Alternatively, such information may be directly delivered to  
decision-support module 210 over a secure connection.

According to another aspect of the present invention, medical module 216  
includes ancillary module 256. Ancillary module 256 includes one or more other  
modules that represent the various hardware and/or software modules of the individual  
10 departments within the medical facility, such as the hospital or clinic, and their associated  
connection to medical module 216 and network 212. As illustrated, ancillary module 256  
may include a pharmacy module 260, laboratory module 262, admit/discharge/transfer  
module 264, radiology 266, and the like. One skilled in the art may identify various other  
modules that may be included within ancillary module 256. For example, ancillary  
15 module 256 may include computer physician order entry systems, other order entry  
systems, and the like.

Generally, pharmacy module 260 maintains information and data representative of  
drugs requested and proscribed for each of a plurality of patients, whether a patient is an  
inpatient or an outpatient. Similarly, laboratory module 262 maintains information and  
20 data representative of the laboratory tests ordered and performed for each of a plurality of  
patients. Admit/discharge/transfer module 264, in this configuration, maintains  
information and data representative of the billing information and scheduling information  
associated with each of a plurality of patients, while radiology module 266 maintains  
information and data representative of the Computed Tomographic (CT) scans, fetal  
25 ultrasounds, magnetic resonance imaging (MRI), mammographs, and X-rays, ordered and  
performed for each of a plurality of patients.

Generally, system 200 suggests the various embodiments or configurations by  
which the present invention may be implemented for various network configurations. For  
example, when network 212 is the Internet, system 200 illustrates the communication of  
30 clinicians and patients with a decision-support module 210 having the configuration of a  
web site. In this manner, decision-support module 210 acts as an application service  
provider where the modules and components of decision-support module 210 are

centrally located and connected to via a secure Internet connection. To access decision-support module 210 a clinician and/or patient pays a regular subscription fee and uses a traditional web browser, such as Microsoft Internet Explorer, Netscape, and the like. This particular configuration reduces the installation costs for those medical facilities that wish to utilize the beneficial properties of the present invention. However, this configuration requires the clinician and/or patient to input the patient information to be stored in patient module 220.

Alternatively, when network 212 is a LAN, system 200 illustrates the communication of clinicians and patients with decision-support module 210 that is integrated with medical module 216, as illustrated by the dotted lines in Figure 2. Such integration may be achieved by connecting inference module 232 of decision-support module 210 directly to application module 254 of medical module 216 by an Internet Inter-Object Request Broker Protocol (IIOP) or remotely by a Remote Method Invocation (RMI). In this configuration, clinicians and patients obtain the decision-supported patient data (or the decision-supported progress note) via a secure intranet using one of a variety of web browsers known to one skilled in the art. In this manner, decision-support module 210 may be integrated with medical module 216 and may receive patient data stored in patient module 220 and/or ancillary module 256. The medical module 216 and the individual modules included within ancillary module 256 may be considered as an electronic medical record (EMR) system that is typically used within the medical field.

In still another configuration, again when network 212 is a LAN, system 200 illustrates the communication of clinicians and patients with decision-support module 210 that is integrated with application server 254 of medical module 216. In this configuration, ancillary module 254 acts as patient module 220 and requests decision-supported patient data (or decision-supported progress notes) from inference module 232 and progress note module 236 directly. This is achieved by interfacing application server 254 with knowledge module 226, whether or not knowledge module 226 resides on application server 254. In this configuration, a clinician receives decision-supported patient data transparently without the clinician switching to a different application or having to learn new software products.

Figures 4 and 5 are flow diagrams representing the operational process of providing medical care by a clinician in an "outpatient" setting, such as at a clinic. The

1 discussions will be generalized with respect to the configuration of system 200 with  
respect to the interaction of decision-support module 210, user module 214, and medical  
module 216 through network 212, i.e., whether network 212 is a LAN, WAN, the  
Internet, and the like. It may be appreciated, that the method steps described herein are  
5 only illustrative of one method of performing the desired function.

Referring now to Figure 4, a description of the methodology of the present  
invention shall be provided as it relates to obtaining decision-supported data by a  
clinician in an outpatient setting, where the patient has known medical conditions, such as  
diabetes. The methodology description refers to Figures 2 and 3, thereby illustrating the  
10 method of processing data through the various illustrative modules and components of the  
present invention.

Initially, in an "outpatient" setting, such as in a clinic, a patient arrives at the clinic  
and is admitted, or otherwise identifies themselves as having an appointment to meet with  
the clinician, as represented by block 300. Upon paying any fees and completing any  
15 admission paper work, the patient may access a user module 214 by providing the  
patient's name, birth date, social security number, or the like. By giving the identification  
information, the patient gains access to system 200, as represented by block 302. For  
example, in one embodiment a patient provides the identification information through a  
cathode ray tube (CRT) monitor with a touch sensitive user interface 246.

20 Upon accessing system 200, decision-support module 210 accesses patient  
specific information contained within patient module 220, as represented by block 304.  
Based upon the patient's identification information, decision-supported patient data from  
decision-support module 210 is used to generate standardized questions to be asked of the  
patient, as represented by block 306. Alternatively, control module 244 may receive the  
25 standardized questions from data storage module 248 of user module 214. In either case,  
the standardized questions may be modified by any of the patient's pre-existing medical  
conditions. For example, in this illustrative example, the patient has diabetes and the  
questions asked by system 200 may be modified by one or more rules to thereby review  
the current medical condition of the patient with respect to their diabetes.

30 As the patient is asked questions, as represented by block 308, and provides  
answers, as represented by block 310, control module 244 tracks the answers and  
transmits the same to decision-support module 210. Upon receiving the answers,

1 inference module 232 and/or knowledge module 226 (with associated rules) evaluate the  
responses, as represented by block 312, to determine whether additional information is  
need to generate a recommendation. Until a recommendation is reached, system 200 will  
continue to ask questions, receive answers and evaluate answers, as represented by  
5 decision block 314.

Once a recommendation is reached, if a recommendation is required, system 200  
generates a decision-supported progress note that may be used by the clinician during a  
physical examination of the patient, as represented by block 316. For example, the  
decision-supported progress note can provide the clinician with a ranked list of  
10 recommendations with side-effects or problems associated with each recommendation.

In the event that the question and answer session results in decision-support  
module 210 identifying educational materials that may aid the patient with their medical  
condition, user module 214 may prompt the patient as to the desirability of obtaining such  
educational materials, as represented by decision block 318. If the patient wishes the  
15 educational materials, user module 214 may retrieve such information from data storage  
248 or alternatively from decision-support module 210 and/or medical module 216 and  
print or otherwise deliver the materials to the patient, as represented by block 320.  
Optionally, system 200 may always provide the patient with the educational material,  
without the patient having the option to select whether they receive the educational  
20 materials.

Following receipt of the educational materials, whether receipt occurs before or  
after the decision-supported progress note is created, the patient receives a brief physical  
exam, such as height, weight, blood pressure, and the like by a clinician's assistant, or  
optionally the clinician, as represented by block 322. The newly obtained physical exam  
25 data is input into system 200 through user interface 246 and the patient data is updated, as  
represented by block 324.

Upon receiving the updated patient data, inference module 232 reevaluates the  
recommendation previously developed in light of the updated patient data, as represented  
by block 326. This new recommendation, as with the previous recommendation may be  
30 based upon not only the medical information contained in knowledge module 226 but  
may be based upon the patient's insurance provider, the cost of the drug or other

1 treatment, effectiveness of the treatment, and such other factors as known by one skilled  
in the art.

Subsequently, decision-support module 210 applies the same or different rules to  
generate a new decision-supported progress note, as represented by block 328, which is  
5 delivered to the clinician so that the clinician may complete the clinician's examination of  
the patient, as represented by block 330.

To complete the "outpatient" process, the clinician may review the questions or  
other information that decision-support module 210 has identified as a medical area  
requiring a more detailed analysis of the patient's medical condition. For example,  
10 although a patient may be visiting the clinician for a scheduled check-up, the patient's  
responses to the posed questions may suggest another medical conditions, such as an  
unknown disease, or other medical condition.

Referring now to Figure 5, an illustrative process for identifying and  
recommending a treatment for an unknown disease is depicted. Continuing with the  
15 above-described illustrative example, a patient with a known disease, such as diabetes, is  
determined to have an unknown disease. Initially, the clinician may review the patient's  
medical history contained within decision-support module 210 or optionally collect new  
patient history or demographic information, as represented by block 340

Following receipt of the demographic information, the clinician may collect  
20 disease information, as represented by block 342. This may be obtained through  
laboratory tests or from the question and answers provided to the clinician by system 200.  
Furthermore, the question and answers used to initially collect current medical  
information may be used to collect medical condition information regarding the patient's  
relatives. Therefore, system 200 may analyze the patient's predisposition for particular  
25 medical conditions in light of the newly gathered or stored patient data.

Let us assume that the unknown medical condition is a disease. Once the disease  
is identified, a clinical classification is identified based upon the disease, as represented  
by block 344. For example, let us assume that the disease is identified as pneumonia; the  
clinical classification may include deciding whether the pneumonia is to be treated with  
30 outpatient therapy or inpatient therapy. Alternatively, the clinician may select an  
undecided choice, thereby allowing system 200 to give the clinician information  
regarding the possible benefits of one or other of the possible therapy regimes. When the

1 clinician is undecided or uncertain as to whether the patient should be treated as an inpatient or an outpatient, the clinician may optionally access or be prompted to access information within knowledge module 226 that gives the clinician the criteria for admission.

5 Following the therapy clinician classification, the acquisition clinician classification may be determined. The clinician may determine whether the medical condition was hospital acquired (HAP) (ventilator associated or non-ventilator associated), nursing home acquired, HIV-associated pneumonia, Cystic Fibrosis-associated pneumonia, or community acquired (CAP).

10 Once the clinical classification is identified, the rules control the manner by which system 200 collects the etiology based on the clinical class, as represented by block 346. This may include distinguishing between an uncertain organism requiring an empiric therapy and an organism identified through laboratory results. For example, the organism may be a gram-positive (GP) bacteria, such as *Streptococcus pneumoniae* (S. pneumoniae) or *Staphylococcus aureus* (S. aureus) or a gram-negative (GN) bacteria, such as *Hemophilus influenzae* (H. influenzae), *Klebsiella pneumoniae* (K. pneumoniae), *Moraxella catarrhalis*, *Pseudomonas aeruginosa* (P. aeruginosa), or *L. pneumophila*. If the organism is an atypical pathogen the clinician may select from a list of appropriate pathogens depending upon the type of acquired pneumonia. For example: (i) an Atypical bacterial, such as *M. pneumoniae* or *Chlamydia pneumoniae*; (ii) *Rickettsiae*, such as *Coxiella burnetii* (Q Fever); (iii) an Acid-fast bacteria, such as *M. tuberculosis* or MAC complex; (iv) a Fungi/Protozoa, such as *Coccidioidomycosis*, *Histoplasmosis*, *Blastomycosis*, *P. carinii*; (v) a virus, such as *Influenza A*, *Influenza B*, *Hantavirus*, and the like. For example, if the pneumonia is community acquired (CAP) the clinician may be given the options of *Legionella*, *Mycoplasma*, *Influenza*, *Chlamydia pneumoniae*, *Chlamydia psittaci*, *Coxiella burnetii* (Q Fever), and the like. Similarly, if the organism is a Pyogenic pathogen and community acquired, the clinician may select from *Streptococcus pneumoniae*, *Hemophilus influenzae*, *Staphylococcus aureus*, Group A *Streptococcus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Neisseria meningitidis*, *Moraxella catarrhalis*, and the like.

Following receipt of the etiology, the rules may present the clinician with various genetic or other susceptibilities of the disease if etiology is organism specific, as

1 represented by block 348. In this manner, the clinician may define the etiology of the  
organism. In this particular example, let us assume that the organism is identified as  
Staphylococcus aureus. The clinician may provide system 200 with information related  
to the organism's susceptibilities within the particular patient. For example, the organism  
5 may be resistant to linezolid, oxacillin, vancomycin, and dalfopristin-quinupristin.  
Alternatively, the clinician may not know the susceptibilities thereby relying on system  
200 to recommend a treatment that may work.

Upon defining any organism susceptibilities, the rules used by inference module  
230 may aid the clinician in defining one or more mitigating factors based upon the  
10 etiology, as represented by block 350. The clinician may define factors that may have  
caused the pneumonia. For example, the patient may have recently aspirated, be  
immunosuppressed, recently received antibiotics, and the like. Additionally, the  
mitigating factors may be specific to whether the organism is identified or whether the  
empiric therapy is to be used for an unknown organism. For example, for an identified  
15 organism the clinician may provide information related to abnormal kidney function,  
Antimicrobial resistance, current or recent treatment failure, and the like. Similarly, if the  
organism is unknown, the clinician may define information and data related to Abnormal  
kidney function, Recurrence/relapse, Age, Comorbidities, Severity/Acuteness of illness,  
Neutropenia, Neutropenia with IV access, Neutropenia and fever despite therapy,  
20 Aspiration, Suspicion of organism (esp. HAP, CF), CD4 count (HIV), Disease stage (CF),  
and the like.

Following the data collection, system 200, and more specifically, decision-support  
module 210 generates a recommendation for treatment of the patient, optionally using the  
information gathered by the clinician, the stored patient data, microbrial susceptibilities  
25 and genetic predispositions based upon the patient's family history and relative's medical  
conditions, the rules, as represented by block 352. Such recommendation may entail  
decision-support module 210 analyzing: (i) patient's drug allergies; (ii) patient's genetic  
variations with regard to drug metabolizing enzymes or genetic predisposition to diseases;  
(iii) genetic variations in the patient's ability to metabolize specific drugs; (iv) drug-drug  
30 interactions; (v) dosing requirements based on height, weight, age, sex, and the like; (vi)  
price; (vii) probability of success for curing the disease; (viii) monographs; (ix)  
antibiograms or antimicrobial-susceptibility patterns; and (x) formulae of the drug.

1       System 200 may also use pharmacogenomic data to select particular medical  
treatment modalities; thereby using a patient's genetic structure to define responses to  
prescribed drugs.. For example, a patient may be found through genetic testing to lack an  
enzyme necessary for a particular drug's metabolism. Hence, decision support module  
5       210 would use such pharamacogenomic information to suggest an alternative drug that  
avoids toxicity and treatment failure, while being consistent with the patient's condition  
and pertinent medical parameters.

          Additionally, recommendations may include analyzing the need for a referral,  
other tests, microbial susceptibility or genetic predispositions to the disease or medical  
10       condition, family history, behavioral and lifestyle changes, and patient education related  
to the medical condition or avoiding the medical condition. In this manner, system 200  
may optionally evaluate the patient's long-term risk for contracting or their predisposition  
or susceptibility to various medical conditions. Thus, decision-supported patient data or a  
decision supported progress note is created.

15       As mentioned throughout, the above-recited process to generate the decision-  
supported patient data and the decision-supported progress note may use one or more,  
rules and provide statements to the clinician to assist the clinician with making an  
informed decision of medical treatment. Such statements and rules, stored in knowledge  
module 226, are used by inference module 232 to make the decision-supported  
20       recommendation for treatment of the medical condition.

          Illustrative rules and statements for the diagnosis and treatment of Pneumonia are  
represented in Tables 1-5 of Figures 6-10. As illustrated, Table 1 contains a plurality of  
rules that may be used by inference module 230 to generate the decision-supported  
patient data and the decision-supported progress note, thereby providing the clinician with  
25       a recommended medical treatment for a medical condition. Tables 2-5 (Figures 7-10)  
contain a number of rules specific to certain information collected by system 200;  
specifically, optionally sequentially activated rules associated with the analysis of  
mitigating factors, susceptibilities, and duration of treatment. One skilled in the art may  
appreciate that various other rules may be appropriate to generate a recommendation for  
30       treatment of Pneumonia.

          The clinician determines whether the recommendation is correct by analyzing this  
recommendation. If correct, the treatment is finalized, as represented by block 332 of

1 Figure 4. Otherwise, system 200 and clinician progress through an iterative process to generate new recommendations based upon other factors that the clinician identifies using the same and/or additional rule specific to other medical conditions identified by the clinician.

5 It may be appreciated that one skilled in the art may perform the method described herein in a variety of manners, such as in differing order of steps, elimination of one or more steps, inclusion of all, some or addition steps, and the like. For example, steps 340-350 need not be performed by the clinician but are alternately performed by system 200 based upon patient data stored within patient module 220 and knowledge module 226.

10 Additionally, the method may include various steps associated with system 200 prompting the clinician to complete a medchart to be sent to the Centers for Disease Control (CDC). Additionally, the above method may require checking with the CDC to determine whether a particular medical condition is gaining prevalence within a given regional area or to provide information to the CDC regarding the prevalence of the medical condition within the area that is served by the medical provider utilizing the

15 beneficial properties of the present invention.

Referring now to Figure 11, an illustrative flow diagram for the treating a patient in an "inpatient" setting is depicted. Let us assume that the patient has a known medical condition, such as a urinary tract infection. During a visit with the patient, such as during

20 "rounds", a clinician accesses system 200 through user module 214. Upon identifying the patient with whom he or she is visiting, as depicted by block 370, user module 214 requests the most up to date decision-supported patient data or decision-supported progress notes for the patient. Subsequently, decision-support module 210, either solely or in combination with medical module 216 gathers patient data for the patient selected,

25 as represented by block 372. This may entail each or a combination of the following: (i) searching patient module 220, with its associated databases 222a-222n (Figure 3); (ii) searching one or more modules of ancillary module 256 (Figure 3) of medical module 216; and (iii) receiving patient data from the clinician through user module 214.

Once decision-support module 210 gathers the patient data, inference module 232

30 of decision-support module 210 updates the decision-supported patient data based upon the most current patient data with the data (such as one or more rules) stored within knowledge module 226, as represented by block 374. Decision-support module 210 then

1 updates the decision-supported progress note for delivery to the clinician. Analysis of the  
patient data to update the progress note may be performed in a similar manner as that  
described with respect to Figure 5.

5 For example, decision-support module 210 reviews the clinical classification of  
the infection defined by the clinician and system 200. In this example, decision-support  
module 210 retrieves information related to the urine collection method, i.e., clean catch,  
Foley catheter, no urine collected, or other method, verifies the interpretation of the  
patient's symptoms and signs made by the clinician, i.e., whether the infection is lower  
10 tract, upper tract, or asymptomatic, and confirms whether the patient is being treated as an  
inpatient or an outpatient. In this example, let us assume that the patient is an inpatient  
and has a lower tract infection.

Upon retrieving the clinical classification, decision-support module 210 retrieves  
the etiology of the organism. This may include an identified or unidentified organism. If  
the organism is unidentified, decision-support module 210 checks to see if any cultures  
15 are pending. This may require decision-support module 210 to communicate with  
ancillary module 256 of medical module 216, and more specifically laboratory module  
262, to determine whether any cultures are pending. Otherwise, decision-support module  
210 analyzes the previous decision-supported patient data and decision-supported  
progress note for data representative of a request for organism cultures.

20 If the organism is identified, decision-support module 210 retrieves the  
information regarding the organism's etiology. For example, as illustrated in Figure 12,  
the infection may be a bacteria, fungi, a parasite, or a virus. If a bacteria, the organism  
may be categorized as having gram-negative rods (GNR), gram-negative cocci (GNC),  
gram positive cocci (GPC), gram-positive rods (GPR), or acid-fast bacteria. In one  
25 embodiment of the present invention, as illustrated in Figure 12, decision-support module  
210 defines the bacteria to a more specific degree, but for illustrative purposes, the  
categorization of the bacteria is sufficient to present one skilled in the art with the  
required information and explanation of the present invention. If the organism is a  
fungus, the fungus may be *Candida* spp. or *Non-candida* spp. Similarly, the particular  
30 parasite or virus may be defined. For this illustrative example, let us assume that the  
patient has *Chlamydia*.

1       Following obtaining the etiology, decision-support module 210 gathers any  
susceptibilities and any mitigating factors. In this particular example, no susceptibilities  
are necessary. In contrast, however, a number of mitigating factors may be displayed or  
presented to the clinician. Such mitigating factors may include, but are not limited to  
5       pregnancy or post-partum state, renal transplant or other immunosuppression, use of  
diaphragm prior to onset, recurrence, early relapse of initial treatment failure, diabetes,  
neurogenic bladder, recent urologic surgery/instrumentation, obstruction or abnormal  
urological anatomy, duration of symptoms for longer than seven (7) days, age less than  
three (3) years, and the like. Each mitigating factor may include a rule stored in  
10       knowledge module 226 that may be used to guide the decision-support process of the  
present invention.

      Upon completing the above analysis, decision-support module 210 generates an  
updated decision-supported patient data and decision-supported progress note with a  
ranked list of recommendations, as represented by blocks 376 and 378. In this example,  
15       decision-support module 210 also identifies whether the existing medical care is  
successful in treating the urinary tract infection and generates a recommendation based  
upon the current success of the regime.

      The above-recited process to generate the decision-supported patient data and the  
decision-supported progress note may use one or more rules and present the clinician with  
20       one or more statements regarding the rule used, as illustrated in Figures 13-19. Such  
statements and rules, stored in knowledge module 226, are used by inference module 232  
to make the decision-supported recommendation for treatment of the medical condition.

      As illustrated, Table 6 contains a plurality of rules that are directed to the general  
decision-supporting process of determining a recommended medical treatment for a  
25       medical condition. The illustrated rules contain illustrative logic used to determine and  
display a particular medical treatment. When the recommended medical treatment is  
displayed to the clinician, the clinician may optionally select to obtain other medical  
treatments that would be equivalent to the medical treatment given to the clinician. For  
example, some of the illustrative rules contain recommended treatments that are  
30       underlined. Such medical treatments have associated equivalent medical treatments that  
the clinician may optionally review and select. For example, the recommended medical  
treatment may be the prescription of a certain classification of drug, such as

1 fluoroquinolone. A clinician may operate user interface 246 to obtain the various  
equivalent medications within the class of fluoroquinolone.

5 Tables 7-11 (Figures 13-18) contain a number of rules specific to certain  
information collected by system 200; specifically, optionally sequentially activated rules  
associated with the mitigating factors, susceptibilities, and duration of treatment. The  
statements and rules contained in Figures 13-18 are specific to the diagnosis and  
treatment of Urinary Tract Infection; however one skilled in the art may appreciate that  
various other rules may be appropriate. Table 12 (Figure 19) depicts illustrative  
10 medications that may be prescribed or recommended by decision-support module 210  
with associated contraindications. Therefore, decision-support module 210 analyzes the  
patient's medical history to verify that the patient is not allergic or resistant to a particular  
recommended medication. If the patient is allergic or resistant, decision-support module  
210 defines a new recommendation for the clinician.

15 As mentioned above, the decision-support progress note, generally, includes all  
pertinent patient data that relate to the recommended treatments suggested by decision-  
support module 210. For example, when a therapeutic regimen is suggested, such as  
when treating the urinary tract infection, the decision-supported patient data includes drug  
name and type, dose, route, interval, daily cost, duration of therapy, critical alerts and  
20 warnings specific to the patient and the drug, patient demographics, logic sectors (rules)  
that are specific to the patient and the medical condition or syndrome being treated that  
led to the suggested treatment, and the like. Such information will be specific to each  
patient. For example, the dose of the therapeutic drug may be defined by decision-  
support module 210 based upon the height, weight, age, gender, and past medical history  
of the patient, current laboratory test values, the patients pharamacogenomic data, and the  
25 like. Although the analysis performed by decision-support module 210 may not be  
illustrated or displayed to the clinician, such information may be provided to the clinician  
via user module 214 if requested by the clinician.

Once a decision-supported progress note is generated for the patient, decision-  
support module 210 delivers the decision-supported progress notes to the user module  
30 214 through which the clinician has accessed system 200, as represented by block 380.

Upon receiving the required patient data (e.g., decision-supported patient data,  
patient data, and other patient specific information), the clinician may perform his or her

1 examination of the patient, as represented by block 382. The examination may be a physical examination, a question and answer session, or a combination thereof. Following the examination, the clinician may update the information stored within user module 214, as represented by block 384.

5 Subsequently, user module 214 connects to decision-support module 210 to generate new decision-supported patient data and a progress note, as represented by blocks 386 and 388. Following receipt of the new decision-supported patient data, the clinician selects the desired medical treatment or regime, as represented by block 390.

10 Alternatively, instead of the clinician asking a number of questions as prompted by the clinician's knowledge and information contained within the decision-supported patient data, a patient may answer a number of questions posed through another user module located at the patient's bed. In this manner, when the clinician examines the patient the clinician merely has to select the desired medical treatment or regime, without connecting to decision-support module 210 to obtain new decision-supported patient data. Hence, steps related to connecting to decision-support module 210 to obtain new decision-supported patient data are optional to the flow diagram depicted in Figure 11.

15 Once the desired medical treatment or regime is selected, the clinician updates decision-support module 210, and optionally communicates with the necessary sub-modules of ancillary module 256 to request the desired treatment, as represented by block 392. For example, in the event that the medical care recommended by the clinician requires laboratory tests, user module 214 connects to laboratory module 262 to schedule such tests and notifies the nurse or other clinician assistant to obtain the necessary blood or other substances to perform the desired tests. Similarly, if a prescription medication is required, user module 214 connects with pharmacy module 260 to obtain the medication.

#### 25 Example

Following hereinafter is a generalized discussion of the manner by which decision-support system 200 may be used to provide the clinician with decision-supported patient data and one or more decision-supported progress notes where the medical condition is Meningitis. The example provides more specific rules and parameters related to Meningitis, while further illustrating the flow of data through system 200.

1 Referring now to Figures 20A-B, a schematic representation of the decision-support process described herein is depicted. As shown, general patient data is obtain by reviewing the medical history or demographic information, as represented by block 400

5 Following receipt of the demographic information, the clinician may collect disease information such as discussed above. For example, the disease information may be obtained through laboratory tests, from the question and answers provided to the clinician, patient data previously collected, based upon susceptibilities and genetic information associated with the patient's relatives, and the like. Once the disease is identified, a clinical classification is identified based upon the medical condition, as  
10 represented by block 402. We are currently assuming that the medical condition meningitis. The clinical classification of meningitis may include determining the duration of the meningitis to thereby decide whether the meningitis is acute or chronic. Different decision-support processes are taken depending if the meningitis is acute or chronic as may be discussed hereinafter.

15 Once the clinical classification is identified, system 200 collects the etiology based on the clinical classification, as represented by block 404. This may include distinguishing between a bacterial, viral, fungal, and an uncertain etiological classification. Subsequently, the etiology of the disease is determined based upon whether the meningitis is acute or chronic. If acute, the infection may be selected from  
20 those listed in block 406 or remain unidentified. Alternatively, system 200 and optionally the clinician may identify the meningitis as chronic, thereby selecting the bacterial, viral, or fungal infection as represented by block 408, or optionally leaving the infection unidentified.

25 Following receipt of the etiology, a clinician may define the susceptibilities of the disease if etiology is organism specific. For example, different organisms may be resilient to different medical treatments. In the case of meningitis, the various rules may provide:

- 30 1. Antibiotic susceptibility list for GNRs (except pseudomonas, Stenotrophomonas, acinetobacter, Hemophilus), may include: Ampicillin/sulbactam, Cephalothin, Cefazidime, Ceftriaxone, Cefotaxime, Ciprofloxacin, Gentamicin, Imipenem, Levofloxacin, Piperacillin, Piperacillin/tazobactam, Trimethoprim/sulfamethoxazole.

- 1           2. Antibiotic susceptibility list for *Pseudomonas* may include: Cefazidime,  
Ciprofloxacin, Gentamicin, Imipenem, Piperacillin, Piperacillin/tazobactam.
- 5           3. Antibiotic susceptibility list for *Staphylococcus* may include: Oxacillin,  
Vancomycin, Rifampin.
4. Antibiotic susceptibility list for *Hemophilus* may include a 3<sup>rd</sup> generation  
cephalosporin.
- 10          5. Similarly, antibiotic susceptibility list for *Neisseria meningitidis* may include a  
3<sup>rd</sup> generation cephalosporin.
6. Susceptibility for *Streptococcus pneumoniae* may include: Chloramphenicol,  
Vancomycin, and defined minimum inhibitory concentration (MIC) for  
15          pencillin, cefotaxime, ceftriaxone,
7. Susceptibility for *S. agalactiae* may include: Ampicillin and Gentamicin.

20           Upon defining any organism susceptibilities, the clinician may define one or more  
mitigating factors based upon etiology, as represented by blocks 410 and 412 in Figure  
20B. The mitigating factors may be specific to whether the organism is identified or  
whether the empiric therapy is to be used for an unknown organism. For example, for an  
identified organism the clinician may provide information related to abnormal kidney  
function, Antimicrobial resistance, current or recent treatment failure, and the like.

25           Similarly, if the organism is unknown, the clinician may define information and data  
related to Abnormal kidney function, Recurrence/relapse, Age, HIV status, Alcoholism,  
Concurrent debilitating disease, Concurrent impaired cellular immunity, recent  
neurosurgery, recent head trauma, presence of V-P shunt, suspected MDR tuberculosis,  
and the like.

30           Following the data collection, system 200, and more specifically, decision-support  
module 210 generates a recommendation for treatment of the patient, by analyzing: (i)  
patient's drug allergies; (ii) patient's genetic variations with regard to drug metabolizing

1 enzymes or genetic predisposition to diseases; (iii) genetic variations in the patient's  
ability to metabolize specific drugs; (iv) drug-drug interactions; (v) dosing requirements  
based on height, weight, age, sex, and the like; (vi) price; (vii) probability of success for  
curing the disease; (viii) monographs; (ix) antibiograms or antimicrobial-susceptibility  
5 patterns; and (x) formulae of the drug. Additionally, recommendations may include  
analyzing the need for a referral, additional tests, microbial susceptibility or genetic  
predisposition to the disease or medical condition, pharmacogenomic data, family history,  
behavioral and lifestyle changes, and patient education related to the medical condition or  
avoiding the medical condition. In this manner, system 200 may optionally evaluate the  
10 patient's long term risk for contracting or their predisposition or susceptibility to various  
medical conditions. Thus, decision-supported patient data or a decision supported  
progress note is created.

The above-recited process to generate the decision-supported patient data and the  
decision-supported progress note may use one or more statements and rules, as illustrated  
15 in Figures 21-24. Such statements and rules, stored in knowledge module 226, are used  
by inference module 232 to make the decision-supported recommendation for treatment  
of the medical condition. As illustrated, Table 13 contains a plurality of rules that are  
directed to the general decision-supporting process of determining a medical treatment for  
a medical condition of Meningitis. Tables 14-16 (Figures 22-24) contain a number of  
20 rules specific to certain information collected by system 200; specifically, optionally  
sequentially activated rules associated with the duration of treatment, mitigating factors,  
and caveats. The statements and rules contained in Figures 21-24 are specific to the  
diagnosis and treatment of Meningitis; however one skilled in the art may appreciate that  
various other rules may be appropriate.

25 The present invention may be embodied in other specific forms without departing  
from its spirit or essential characteristics. For example, embodiments of the present  
invention are also disclosed in copending United States Patent Application entitled  
"Systems and Methods for Communicating Between a Decision-Support System and One  
or More Mobile Information Devices", filed September 21, 2000, which is incorporated  
30 herein in its entirety by reference. The described embodiments are to be considered in all  
respects only as illustrative and not restrictive. The scope of the invention is, therefore,  
indicated by the appended claims rather than by the foregoing description. All changes

1 that come within the meaning and range of equivalency of the claims are to be embraced  
within their scope.

What is claimed is:

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- 1           1. In a decision-support system having data stored in a knowledge base, a  
method for delivering decision-supported patient data to a clinician to aid the clinician  
with the diagnosis and treatment of a medical condition, the method comprising the steps  
of:
- 5           (a) gathering patient data from a patient in response to a decision-  
supported questionnaire;
- (b) evaluating the patient data with the knowledge base to generate  
decision-supported patient data, the decision-supported patient data comprising a  
medical condition diagnosis of the patient and one or more medical care  
10       recommendations; and
- (c) presenting the clinician with the decision-supported patient data  
specific to the patient in a format that assists the clinician in treating the patient.
2. A method as recited in claim 1, further comprising the step of transmitting  
the decision-supported patient data to a user module.
- 15       3. A method as recited in claim 1, further comprising the step of generating a  
decision-supported progress note from the decision-supported patient data.
4. A method as recited in claim 1, further comprising the step of tracking the  
success of the one or more medical care recommendations in treating the patient's  
medical condition.
- 20       5. A method as recited in claim 4, wherein the success of the one or more  
medical care recommendations is delivered to a third party.
6. A method as recited in claim 1, further comprising the step of requesting  
patient data by querying one or more ancillary modules.
- 25       7. A method as recited in claim 6, wherein the requesting step comprising  
requesting the patient data on demand by a mobile information device.
8. A method as recited in claim 6, wherein the requesting step comprising  
requesting real-time patient data by a mobile information device synchronizing with at  
least one of (i) a decision-support module and (ii) a medical module.
- 30       9. A method as recited in claim 1, further comprising the step of broadcasting  
patient data to a clinician.

- 1           10. A method as recited in claim 9, wherein the step of broadcasting patient data comprising broadcasting patient data containing at least one alert upon the occurrence of an alert event.
- 5           11. A method as recited in claim 9, wherein the step of broadcasting patient data comprising broadcasting patient data following a defined schedule.
12. A method as recited in claim 1, wherein the knowledge base comprises at least one database containing expert medical information.
13. A method as recited in claim 1, wherein the evaluating step comprises evaluating the patient data against patient data stored in a patient module.
- 10          14. A method as recited in claim 1, wherein the gathering step comprising the step of gathering patient data via a user interface, the user interface comprising at least one of a graphical user interface, an interactive user interface, a voice recognition user interface or a textual user interface.
15. A method as recited in claim 1, wherein the gathering step comprising:
- 15           (a) asking at least one question related to the patient's health;
- (b) receiving at least one answer to the at least one question;
- (c) generating at least one additional question based upon the at least one answer.
16. A method as recited in claim 15, wherein the generating step comprising generating at least one additional question based upon the at least one answer and the data stored in the knowledge base.
- 20          17. A method as recited in claim 1, wherein the format of the decision-supported patient data comprises summarized decision-supported patient data.
18. A method as recited in claim 1, wherein the format of the decision-supported patient data comprises a decision-supported progress note.
- 25          19. A method as recited in claim 1, wherein the evaluating step comprises:
- (a) collecting medical condition information;
- (b) collecting a clinical classification of the medical condition;
- 30           (c) collecting data representative of one or more causes of the medical condition;
- (d) collecting susceptibilities of the medical condition if the one or more causes of the medical condition is organism specific;

1 (e) collecting mitigating factors based on the one or more causes of the medical condition; and

(f) evaluating the medical condition, the clinical classification, the one or more causes, the susceptibilities, and the mitigating factors to generate  
5 decision-supported patient data comprising at least one medical condition and at least one medical care recommendation.

20. A method as recited in claim 19, further comprising:

(a) collecting a patient's genetic and/or environmental susceptibility to disease; and

10 (b) collecting genetic variations of the patient to the patient's drug metabolizing enzymes.

21. A method as recited in claim 19, further comprising the step of collecting the patient's susceptibilities and predispositions for long term risk based upon the patient's family history and patient data associated with one or more relatives of the  
15 patient.

22. A method as recited in claim 19, further comprising the step of collecting patient data from genetic tests to evaluate medical condition to generate the at least one medical recommendation.

23. A method as recited in claim 22, wherein at least one recommendation  
20 comprises at least one of (i) drug selection, (ii) drug duration, (iii) drug route, (iv) drug interval, (v) drug usage, and (vi) daily cost.

24. A method as recited in claim 19, further comprising the step of collecting patient data from pharmacogenomics data to generate at least one medical recommendation.

25 25. A computer-readable medium having computer-executable instructions for performing the steps recited in claim 1.

26. In a decision-support system having data stored in a knowledge base and patient data, a method for delivering a decision-supported progress note to a clinician to aid the clinician with the diagnosis and treatment of a medical condition, the method  
30 comprising the steps of:

- 1           (a) evaluating patient data stored in a patient module with the data  
stored in the knowledge base to generate a decision-supported progress note  
comprising decision-supported patient data; and
- 5           (b) presenting the clinician with the decision-supported progress note  
in a format that assists the clinician in treating each patient.
27. A method as recited in claim 26, further comprising the step of  
transmitting the decision-supported progress note to a user module.
28. A method as recited in claim 27, wherein the user module performs the  
step of presenting the clinician with the decision-supported progress note.
- 10          29. A method as recited in claim 26, further comprising the step of tracking  
the success of the one or more medical care recommendations in treating the patient's  
medical condition.
30. A method as recited in claim 26, wherein the decision-supported progress  
note comprises at least one referral to at least one another clinician.
- 15          31. A method as recited in claim 26, further comprising the step of gathering  
patient data via a user interface, the user interface comprising an interface selected from  
the group consisting of a graphical user interface, an interactive user interface, a voice  
recognition user interface and a textual user interface.
- 20          32. A method as recited in claim 26, further comprising the steps of:
- (a) asking at least one question related to the patient's health;
  - (b) receiving at least one answer to the at least one question;
  - (c) generating at least one additional question based upon the at least  
one answer.
- 25          33. A method as recited in claim 32, wherein the step comprises generating at  
least one additional question based upon the at least one answer and the data stored in the  
knowledge base.
34. A method as recited in claim 32, wherein the step comprises generating at  
least one questions regarding the health of one or more of the patient's relatives.
- 30          35. A method as recited in claim 26, wherein the format of the decision-  
supported patient data comprises a format selected from the group consisting of  
summarized decision-supported patient data and a decision-supported progress note.

- 1           36. A method as recited in claim 26, further comprising the step of authorizing  
the at least one medical care recommendation.
37. A method as recited in claim 36, further comprising the step of generating  
at least one billing code and at least one authorization documentation for the at least one  
5   medical care recommendation.
38. A method as recited in claim 26, wherein the evaluating step comprises:
- (a) collecting medical condition information;
- (b) collecting clinical classification of the medical condition;
- (c) collecting data representative of one or more causes of the medical  
10   condition;
- (d) collecting susceptibilities of the medical condition if the one or  
more causes of the medical condition is organism specific;
- (e) collecting mitigating factors based on the one or more causes of the  
medical condition; and
- 15           (f) evaluating the medical condition, clinical classification, one or  
more causes, susceptibilities, and mitigating factors to generate decision-  
supported patient data comprising at least one medical condition and at least one  
medical care recommendation.
39. A method as recited in claim 38, further comprising:
- 20           (a) collecting a patient's genetic and/or environmental susceptibility to  
disease; and
- (b) collecting genetic variations of the patient to the patient's drug  
metabolizing enzymes.
40. A method as recited in claim 38, further comprising collecting genetic data  
25   and family history from the patient.
41. A method as recited in claim 40, further comprising analyzing the genetic  
data and the family history of the patient to determine one or more causes of the medical  
condition.
42. A method as recited in claim 38, further comprising collecting  
30   pharmacogenomic data related to the patient.

- 1           43. A method as recited in claim 42, further comprising analyzing the pharmacogenomic data of the patient to determine the one or more causes of the medical condition.
- 5           44. A method as recited in claim 26, wherein the data stored in the knowledge base comprises one or more rules and one or more statements.
45. A method as recited in claim 44, wherein the one or more rules comprises at least one rule specific to the medical condition, the at least one rule being capable of generating decision-supported patient data based upon the stored patient data.
- 10          46. A method as recited in claim 44, wherein the one or more rules comprises at least one rule specific to the medical condition, the at least one rule being capable of generating decision-supported patient data based upon the stored patient data and patient data newly gathered.
47. A method as recited in claim 44, wherein the one or more rules comprising:
- 15               (b) at least one duration rule;
- (c) at least one susceptibility rule; and
- (c) at least one mitigating factor rule.
48. A method as recited in claim 26, further comprising the step of authorizing at least one referral.
- 20          49. A method as recited in claim 48, further comprising the step of delivering the at least one referral to a third party insurance provider.
50. A method as recited in claim 26, wherein presenting step comprises delivering the decision-supported progress note to at least one of: (i) a mobile information device; (ii) a third party; and (iii) a clinician's assistant.
- 25          51. A method as recited in claim 50, wherein the decision-supported progress note comprises at least one of: (i) a medical condition diagnosis; (ii) at least one medical care recommendation; and (iii) at least one alert.
52. A method as recited in claim 26, further comprising the step of requesting patient data by querying one or more ancillary modules.
- 30          53. A method as recited in claim 52, wherein the requesting step comprising requesting real-time patient data on demand by querying one or more ancillary modules by a wireless mobile information device.

- 1           54. A method as recited in claim 53, wherein the mobile information device comprises a modem and a browser.
55. A computer-readable medium having computer-executable instructions for performing the steps recited in claim 26.
- 5           56. A computer program product for implementing a method for delivering decision-supported patient data to a clinician via a user module to aid the clinician with the diagnosis and treatment of a medical condition, the computer program product comprising:
- at least one computer readable medium carrying computer-executable instructions for implementing the method, wherein the computer-executable instructions comprise:
- program code means for gathering patient data from a patient in response to a decision-supported questionnaire to define patient data;
- program code means for evaluating the patient data with the knowledge base to generate decision-supported patient data for the patient, the decision-supported patient data comprising at least one medical condition diagnosis of the patient and at least one medical care recommendation; and
- program code means for presenting the clinician with the decision-supported patient data specific to the patient in a format that assists the clinician in treating the patient.
- 20           57. A computer program product as recited in claim 56, wherein the program code means for gathering the patient data and the program code means for presenting the clinician with the decision-supported patient data are contained on one of the at least one computer readable medium.
- 25           58. A computer program product as recited in claim 56, further comprising program code means for transmitting the decision-supported patient data to the user module.
- 30           59. A computer program product as recited in claim 56, further comprising program code means for generating a decision-supported progress note from the decision-supported patient data.

- 1           60. A computer program product as recited in claim 59, wherein the decision-supported progress note comprises alerts to the medical care recommendations generated.
61. A computer program product as recited in claim 56, wherein the decision supported progress note tracks the success and failure of the one or more medical care  
5       recommendations in treating the patient's medical conditions.
62. A computer program product as recited in claim 56, further comprising the step of transmitting data representative of the success and failure of the one or more medical care recommendations to a third party.
- 10          63. A computer program product as recited in claim 56, wherein the knowledge base comprises at least one database containing expert medical data.
64. A computer program product as recited in claim 56, wherein the evaluating program code means comprises program code means for evaluating the patient data against patient data stored in a patient module.
- 15          65. A computer program product as recited in claim 64, wherein the patient module comprises at least one database.
66. A computer program product as recited in claim 56, wherein program code means for gathering comprises program code means for gathering patient data via a user interface, the user interface comprising a graphical user interface, an interactive user interface, a voice recognition user interface or a textual user interface.
- 20          67. A computer program product as recited in claim 56, wherein program code means for gathering comprises:
- (a) program code means for asking at least one question related to the patient's health;
- 25           (b) program code means for receiving at least one answer to the at least one question;
- (c) program code means for generating at least one additional question based upon the at least one answer.
- 30          68. A computer program product as recited in claim 67, wherein the program code means for generating comprises program code means for generating at least one additional question based upon the at least one answer and the data stored in the knowledge base.

1           69. A computer program product as recited in claim 56, wherein the format of the decision-supported patient data comprises summarized decision-supported patient data.

5           70. A computer program product as recited in claim 56, wherein the decision-supported patient data is incorporated within a decision-supported progress note.

71. A computer program product as recited in claim 70, wherein the decision-supported progress note comprises data representative of a qualitative and a quantitative analysis of an assessment of the patient data and the at least one medical care recommendation.

10          72. A computer program product as recited in claim 56, wherein the program code means for evaluating the patient data generates decision-supported patient data comprising a plurality of medical condition diagnosis of the patient and a plurality of medical care recommendations.

15          73. A computer program product as recited in claim 72, wherein the plurality of medical care recommendations is in a rank ordered list.

74. In a decision-support system having data stored in a knowledge base, a method for delivering decision-supported patient data to a clinician to aid the clinician with the diagnosis and treatment of a medical condition, the method comprising the steps of:

20           (a) gathering patient data from a patient in response to a decision-supported questionnaire;

          (b) delivering the patient data to a decision-support module configured to evaluate the patient data with the knowledge base to generate decision-supported patient data for the patient, the decision-supported patient data comprising a medical condition diagnosis of the patient and one or more medical care recommendations; and

25

          (c) presenting the clinician with the decision-supported patient data received from the decision-support module in a format that assists the clinician in treating the patient.

30          75. In a decision-support system having data stored in a knowledge base, a method for delivering decision-supported patient data to a clinician to aid the clinician

1 with the diagnosis and treatment of a medical condition, the method comprising the steps  
of:

(a) receiving patient data gathered from a patient in response to a  
decision-supported questionnaire;

5 (b) evaluating the patient data with the knowledge base to generate  
decision-supported patient data for the patient, the decision-supported patient data  
comprising a medical condition diagnosis of the patient and one or more medical  
care recommendations; and

10 (c) delivering the decision-supported patient data to a user module for  
presenting the clinician with the decision-supported patient data specific to the  
patient in a format that assists the clinician in treating the patient.

76. A decision-support support system, comprising:

15 (a) a decision-support module configured to generate decision-  
supported patient data specific to each patient that a clinician is to examine in a  
defined period, the decision-support module comprising:

(i) a knowledge module configured with data representative of  
expert knowledge within the medical field;

(ii) a patient module configured to store patient data; and

20 (iii) an inference module communicating with the knowledge  
module and the patient module, the inference module being configured to  
generate a decision-supported progress note; and

(b) a user module in communication with the decision-support module  
and adapted to present the decision-supported progress note to the clinician in a  
configuration that assists the clinician in treating each patient.

25 77. A system as recited in claim 76, wherein the knowledge module comprises  
a plurality of databases.

78. A system as recited in claim 77, wherein the decision-support module  
communicates with a medical module to generate the decision-supported progress note.

30 79. A system as recited in claim 76, wherein the medical module comprises a  
plurality of ancillary modules.

80. A system as recited in claim 79, wherein decision-support module receives  
patient data from the user module.

- 1           81. A system as recited in claim 76, wherein the user module is in real-time communication with the decision-support module.
82. A system as recited in claim 76, wherein the user module comprises a wireless communication with the decision-support module.
- 5           83. A system as recited in claim 82, wherein the user module communicates with the decision-support module by a network selected from the group consisting of: (i) a local area network; (ii) a wide area network; (iii) the Internet; (iv) a wireless network; (v) a real-time network; and (vi) a packetized network.
84. A system as recited in claim 76, wherein the user module comprises a user  
10 interface, the user interface configured to present the clinician with the decision-supported patient data in a configuration that assists the clinician in treating each patient.
85. A system as recited in claim 84, wherein the user interface is a web browser.
86. A decision-support support system for providing a clinician with real-time  
15 decision-supported patient data specific to each patient that the clinician is to examine in a defined time period, comprising:
- (a) a decision-support module configured to generate a decision-supported progress note specific to each patient, the decision-supported progress note comprising data representative of at least one medical condition and at least  
20 one medical care recommendation, each of the at least one medical condition and at least one medical care recommendation being generated from patient data, stored patient data, and knowledge base data; and
- (b) a user module in real-time communication with the decision-support module and adapted to present and the decision-supported progress note  
25 in real-time to the clinician.
87. A system as recited in claim 86, wherein the stored patient data comprises data representative of preexisting and past medical care.
88. A system as recited in claim 87, wherein the current patient data comprises  
30 data collected from the patient as a patient responds to at least one question asked to the patient by the user module.

1 89. A system as recited in claim 88, wherein the at least one question is  
dynamically generated by the decision-support module in response to a previously asked  
at least one question.

5 90. A system as recited in claim 88, wherein the at least one question is  
dynamically generated by the decision-support module in response to at least one of: (i) a  
previously asked at least one question; (ii) stored patient data; and (iii) knowledge base  
data.

91. A system as recited in claim 86, wherein the knowledge base data  
comprises data stored within a knowledge module.

10 92. A system as recited in claim 86, wherein the decision-support module  
communicates with the user module via a network.

93. A system as recited in claim 92, wherein the network is selected from a  
group consisting of (i) a local area network, (ii) a wide area network, (iii) a wireless  
network, (iv) a packetized network, and (v) a real-time network.

15 94. A system as recited in claim 86, wherein the decision-support module  
communicates with a medical module to generate the decision-supported patient data.

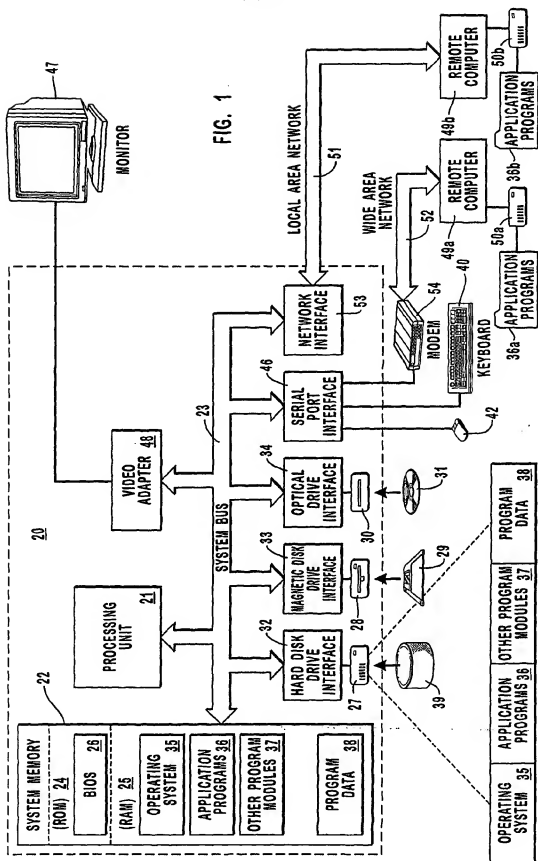
95. A system as recited in claim 86, wherein the medical module comprises a  
plurality of ancillary modules, a web module, and an application module.

20 96. A system as recited in claim 86, wherein decision-support module receives  
patient data from the user module.

97. A system as recited in claim 86, wherein the decision-support module  
comprises a billing module.

98. A system as recited in claim 86, wherein the decision-supported progress  
note comprises data representative of a critical information.

25 99. A system as recited in claim 98, wherein the critical information is one or  
more warnings.



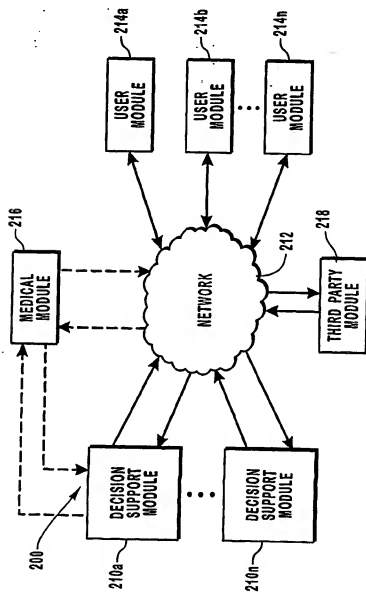


FIG. 2

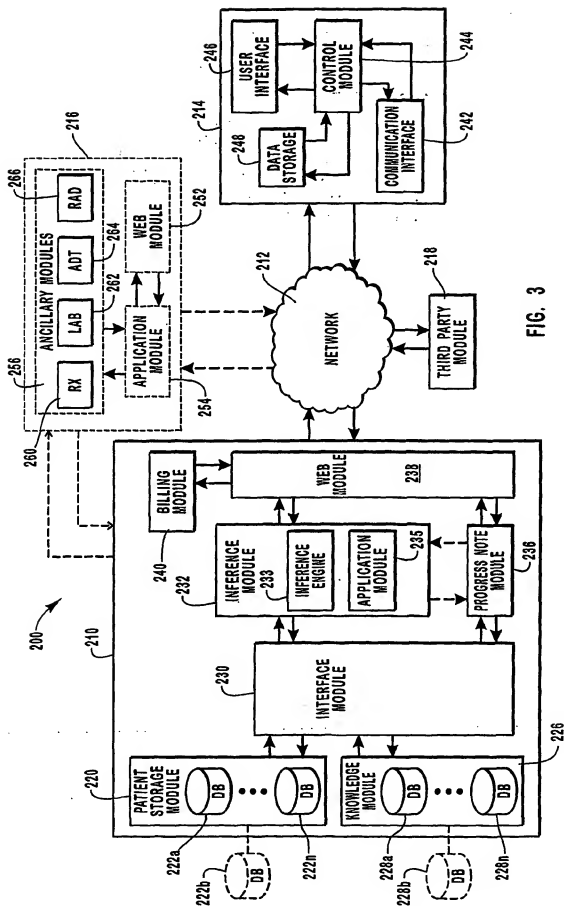


FIG. 3

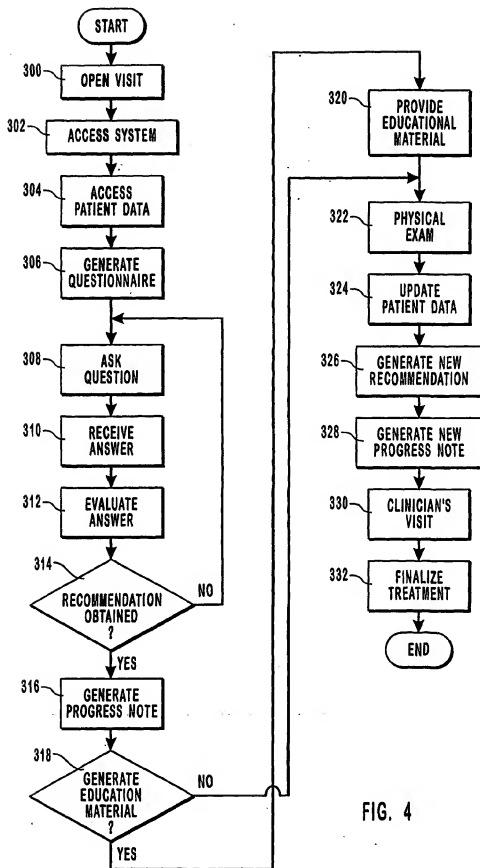


FIG. 4

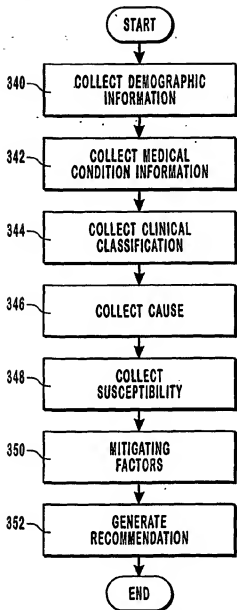


FIG. 5

TABLE 1

#	Statement	Rule
1	Coverage includes <i>Legionella</i> and potentially resistant gram negative rods	If ventilator or non-ventilator HAP and organism unknown and interval from admission > 5 days and (severity is severe or recent prior antibiotics) and <i>Legionella</i> cases identified, then (ceftazidime + ciprofloxacin), (aztreonam + ciprofloxacin (admitted through intravenous)(IV)), piperacillin/tazobactam + macrolide IV
2	Coverage includes resistant gram negative rods because of risk factors.	If ventilator or non-ventilator HAP and organism unknown and interval from admission > 5 days and (severity is severe or recent prior antibiotics), then piperacillin/tazobactam, (ceftazidime + ciprofloxacin), (aztreonam + ciprofloxacin IV)
3	Coverage includes hospital-acquired gram negative rods.	If ventilator or non-ventilator HAP and organism unknown and interval from admission > 5 days, then piperacillin/tazobactam, ceftazidime, ciprofloxacin IV.
4	The recommended therapy is highly active against anaerobes. The onset of aspiration pneumonia is relatively soon after admission.	If ventilator or non-ventilator HAP and organism unknown and admission interval < 6 days and aspiration, then (clindamycin + FQ IV), (metronidazole + FQ IV), ampicillin/sulbactam, (metronidazole IV + 3 <sup>rd</sup> gen cep IV) (clindamycin + aztreonam)
5	Therapy directed toward community- and hospital-acquired organisms because of relatively short interval since admission.	If ventilator or non-ventilator HAP and organism unknown and interval from admission < 6 days, then FQ IV, 3 <sup>rd</sup> gen cep IV + macrolide (admitted orally)(PO)), (clindamycin IV + aztreonam)
6	Therapy directed against hospital-acquired resistant gram negative rods	If ventilator and organism unknown and sputum gram stain GNR, then imipenem, (ceftazidime + ciprofloxacin), (ceftazidime + gentamicin), (ciprofloxacin + gentamicin)
7	Empiric antibiotic coverage weighted toward gram positive cocci because of sputum gram stain results	If ventilator and organism unknown and sputum gram stain GPC, then (vancomycin + ceftazidime), (vancomycin + ciprofloxacin), (nafcillin + ciprofloxacin), (nafcillin + ceftazidime)

FIG. 6A

TABLE 1 (cont'd)

#	Statement	Rule
8	Broad spectrum antibiotics recommended because of patient location and/or risk factors.	If CAP and (ICU or (ward and neutropenia)) and organism unknown, then (3 <sup>rd</sup> gen cep + FQ IV), (piperacillin/tazobactam + macrolide IV), (imipenem + macrolide IV), (vancomycin + ciprofloxacin IV)
9	The recommended therapy is highly active against anaerobes. The infection is community-acquired.	If CAP and inpatient and organism unknown and (aspiration or putrid sputum or lung abscess suspected), then clindamycin IV, (penicillin + metronidazole), ampicillin/sulbactam
10	The recommended therapy is highly active against anaerobes	If CAP and outpatient and organism unknown and aspiration, then amoxicillin/clavulanate, clindamycin PO, (amoxicillin + metronidazole)
11	Empiric antibiotics for hospitalized patients with community-acquired pneumonia includes coverage for common pyogenic organisms such as <i>S. pneumoniae</i> as well as "atypical" pathogens.	If CAP and ward and organism unknown, then (3 <sup>rd</sup> gen cep IV + macrolide PO), (FQ IV), (vancomycin + macrolide IV),
12	The recommended oral antibiotic is active against most pathogens associated with community-acquired pneumonia.	If CAP and outpatient and organism unknown and age < 60, then macrolide PO, amoxicillin, FQ PO not cipro, doxycycline.
13	The recommended oral antibiotic is active against pathogens commonly associated with community-acquired pneumonia among patients within this age range.	If CAP and outpatient and organism unknown, and age ≥ 60, then amoxicillin-clavulanate, FQ PO not cipro, cefuroxime PO, macrolide PO
14	Patients who do not respond to outpatient macrolide or beta-lactam therapy may be treated with a fluoroquinolone or, alternatively, admitted to the hospital for intravenous therapy and further	If CAP and outpatient and organism unknown and macrolide/penicillin treatment failure, then FQ PO not cipro, (3 <sup>rd</sup> gen cep IV + macrolide PO)

TABLE 1 (cont'd)

#	Statement	Rule
15	The recommended oral antibiotic is active against most pathogens associated with community-acquired pneumonia.	If CAP and outpatient and organism unknown and one or more co-morbidities, then FQ PO not cipro, macrolide, amoxicillin/clavulanate.
16	The recommended therapy is effective against <i>Legionella</i> . If the patient is critically ill, add rifampin 600 mg PO/day	If CAP or HAP and organism <i>Legionella</i> , then FQ IV, macrolide IV, macrolide IV + FQ IV, macrolide IV + ciprofloxacin,
17	The recommended therapy is active against <i>P. aeruginosa</i> and <i>S. aureus</i>	If organism <i>P. aeruginosa</i> and <i>S. aureus</i> , then piperacillin/tazobactam, imipenem, (ceftazidime + vancomycin), (ciprofloxacin IV + vancomycin)
18	The recommended therapy is active against <i>P. aeruginosa</i> and <i>S. pneumoniae</i>	If organism <i>P. aeruginosa</i> and <i>S. pneumoniae</i> , then imipenem, piperacillin, ceftazidime + FQ IV not cipro,
19	The recommended therapy is highly active against <i>P. aeruginosa</i> . Combination antibiotic therapy is generally preferred for treatment of pseudomonal pneumonia to reduce the likelihood of emergence of resistance.	If (CAP or HAP) and organism <i>P. aeruginosa</i> , then (ceftazidime + tobramycin), (piperacillin + tobramycin), (imipenem + tobramycin), (ciprofloxacin IV + tobramycin), (ceftazidime + ciprofloxacin IV), (piperacillin + ciprofloxacin IV), (imipenem + ciprofloxacin)
20	The recommended therapy is active against <i>Acinetobacter</i> .	If CAP or HAP and organism <i>Acinetobacter</i> , then imipenem, ceftazidime, ampicillin/sulbactam
21	The recommended therapy is active against gram negative rods which may become resistant to 3 <sup>rd</sup> generation cephalosporins through overproduction of beta-lactamases.	If CAP or HAP and organism <i>Enterobacter</i> or <i>Serratia</i> or <i>Citrobacter</i> , then cefipime, imipenem, 3 <sup>rd</sup> gen ceph + FQ IV, 3 <sup>rd</sup> gen ceph + gentamicin
22	The recommended therapy is active against gram negative rods.	If CAP or HAP and organism <i>E. coli</i> or <i>Klebsiella</i> , then 3 <sup>rd</sup> gen ceph IV, FQ IV, piperacillin/tazobactam, imipenem

TABLE 1 (cont'd)

#	Statement	Rule
23	The recommended therapy is active against <i>Stenotrophomonas</i>	If CAP or HAP and organism <i>Stenotrophomonas</i> , then TMP/SMX IV, doxycycline, ticarcillin/clavulanate
24	The recommended therapy is active against gram negative rods.	If CAP or HAP and organism other GNR, then cefipime, imipenem, FQ IV, 3 <sup>rd</sup> gen cep + gentamicin
25	The recommended therapy is active against <i>S. aureus</i> . Vancomycin is preferred when the rate of methicillin resistance exceeds 10%.	If (CAP or HAP) and organism <i>S. aureus</i> and susceptibility unknown, vancomycin, nafcillin, ceftazolin
26	The recommended therapy is active against <i>S. aureus</i> .	If (CAP or HAP) and organism <i>S. aureus</i> and susceptibility known, then oxacillin, vancomycin, linezolid, dalbapristin/quinupristin
27	The recommended therapy is active against <i>H. influenzae</i>	If ((CAP and inpatient) or HAP) and organism <i>H. influenzae</i> , then 3 <sup>rd</sup> gen cep, FQ IV, ampicillin.
28	The recommended therapy is active against <i>H. influenzae</i>	If ((CAP and inpatient) or HAP) and organism <i>H. influenzae</i> , then 3 <sup>rd</sup> gen cep, FQ IV, ampicillin.
29	The recommended therapy is appropriate for <i>S. pneumoniae</i> when susceptibility is not yet known.	If (((CAP and inpatient) and (((CAP and inpatient) or HAP) and organism <i>S. pneumoniae</i> and susceptibility unknown), then 3 <sup>rd</sup> gen cep IV, FQ IV not cipro, macrolide IV, vancomycin
29	The recommended anti-pneumococcal antibiotic is based on the indicated susceptibility results.	If ((CAP and inpatient) or HAP) and organism <i>S. pneumoniae</i> and susceptibility known, then ampicillin, 3 <sup>rd</sup> gen cep IV, macrolide IV, FQ IV not cipro, vancomycin
30	The recommended oral therapy is appropriate for <i>S. pneumoniae</i> when susceptibility is not yet known.	If CAP and outpatient and organism <i>S. pneumoniae</i> and susceptibility unknown and outpatient, then FQ PO not cipro, amoxicillin, macrolide PO, cefuroxime PO.
31	The recommended oral therapy is active against <i>S.</i>	If CAP and outpatient and organism <i>S. pneumoniae</i> and susceptibility known and outpatient, then

TABLE 1 (cont'd)

#	Statement	Rule
31	The recommended oral therapy is active against <i>S. pneumoniae</i>	If CAP and outpatient and organism <i>S. pneumoniae</i> and susceptibility known and outpatient, then amoxicillin, macrolide PO, FQ PO not cipro
32	The recommended therapy is reliably active against group A strep.	If organism Group A Strep, then Penicillin G, ampicillin IV, clindamycin IV, cefazolin.
33	The recommended therapy is active against <i>Neisseria meningitidis</i>	If organism <i>Neisseria meningitidis</i> , then penicillin G, 3 <sup>rd</sup> gen ceph, FQ IV
34	The recommended therapy is active against <i>Moraxella</i>	If organism and ((CAP and inpatient) or HAP) and organism <i>Moraxella catarrhalis</i> , then 3 <sup>rd</sup> gen ceph, ampicillin/sulbactam, FQ IV
35	The recommended therapy is active against <i>Moraxella</i>	If organism and CAP and outpatient and organism <i>Moraxella catarrhalis</i> , then cefuroxime PO, TMP/SMX, amoxicillin/clavunolate, FQ PO
36	The recommended therapy is active against mycoplasma	If CAP or HAP and organism mycoplasma, then macrolide PO, doxycycline PO, FQ PO
37	The recommended therapy is active against <i>Chlamydia</i>	If CAP or HAP and organism <i>Chlamydia psittaci</i> or <i>Chlamydia pneumoniae</i> , then doxycycline PO, macrolide PO, FQ PO
38	The recommended therapy is active against Q fever	If CAP and organism <i>Coxiella burnetii</i> , then doxycycline PO, chloramphenicol
39	The recommended therapy is active against influenza virus.	If CAP or HAP and organism influenza, then rimantidine, oseltamivir

FIG. 6E

TABLE 2 (Mitigating factor rules (optionally sequential))

If HAP and non-ventilator, then query "Clinically severe?", Interval from admission > 5 days?, Recent prior antibiotics?, Have nosocomial Legionella cases been identified at this institution and is the patient immunosuppressed?

If HAP and ventilator, then query "Clinically severe?", Interval from admission > 5 days?, Recent prior antibiotics?, "Sputum gram stain demonstrates gram negative rods?", "Sputum gram stain demonstrates gram positive cocci?"

If CAP, then query "Is the patient neutropenic?", "Did the patient fail treatment with penicillin or macrolide type antibiotics?", "Putrid sputum or lung abscess suspected?"

## FIG. 7

TABLE 3 (Interpretation of susceptibility rules (not sequential))

- 1 If ampicillin MIC > 1 ug/ml, then interpret *S. pneumoniae* as resistant to ampicillin
- 2 If ceftriaxone or cefotaxime MIC > 1.0 ug/ml, then interpret *S. pneumoniae* as resistant to 3<sup>rd</sup> gen ceph

## FIG. 8

TABLE 4 (Duration rules (sequential))

- 1 If organism legionella or gram negative rod or Mycoplasma or Chlamydia pneumoniae or Chlamydia psittaci or Coxiella burnetii then state "Recommended duration is 21 days"
- 2 If lung abscess suspected, state "Duration is based on response to therapy"
- 3 State "Recommended duration of therapy is 14 days"

## FIG. 9

TABLE 5 (Caveats (not sequential))

- 1 If inpatient, then caveat "If clinical response is satisfactory after 2 – 3 days and GI absorption is adequate, therapy may be switched to an oral agent based on organism identification and susceptibility
- 2 If aspiration and inpatient and interval from admission >5 days and recommended antibiotic not imipenem or piperacillin/tazobactam, then caveat "Aspiration pneumonia in hospitalized patients is most often due to aerobic gram negative and gram positive pathogens which colonize the oropharynx after admission. If anaerobes strongly suspected then clindamycin or metronidazole may be added"
- 3 If organism *S. pneumoniae* and susceptibility unknown, then caveat "Cefotaxime or ceftriaxone are adequate for empiric therapy of pneumococcal pneumonia because the prevalence of high level cefotaxime or ceftriaxone resistance (MIC > 2 ug/ml) is still less than 5% in adults.

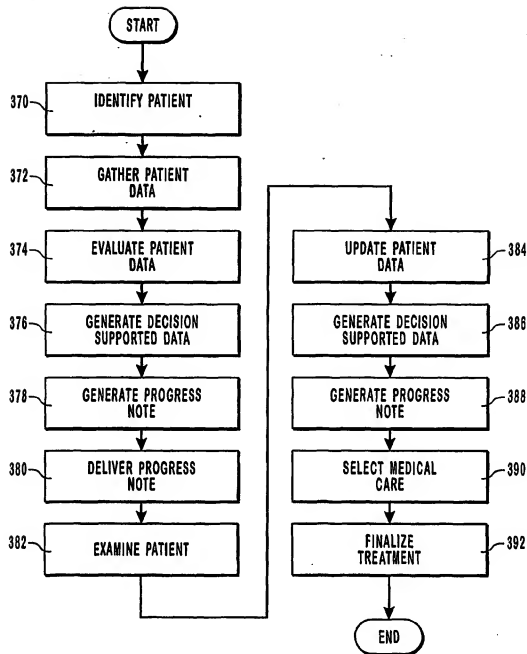


FIG. 11

Etiologic classification Organism identified	Organism uncertain/empiric therapy
<b>Bacteria</b>	
<b>Gram negative rods</b>	
<i>E. coli</i>	
<i>Klebsiella oxytoca</i>	
<i>Klebsiella pneumoniae</i>	
<i>Enterobacter</i> spp.	
<i>Proteus mirabilis</i>	
<i>Pseudomonas aeruginosa</i>	
<b>Other</b>	
<i>Acinetobacter</i> spp.	
<i>Burkholderia cepacia</i>	
<i>Citrobacter</i> spp.	
<i>Gardnerella vaginalis</i>	
<i>Haemophilus influenzae</i>	
<i>Haemophilus parainfluenzae</i>	
<i>Morganella</i> spp.	
<i>Proteus vulgaris</i>	
<i>Providencia</i> spp.	
<i>Salmonella</i> spp.	
<b>Gram negative cocci</b>	
<i>Neisseria gonorrhoeae</i>	
<b>Gram positive cocci</b>	
<i>Enterococcus faecalis</i>	
<i>Staphylococcus aureus</i>	
<i>Staphylococcus coagulase-negative</i>	
<i>Staphylococcus saprophyticus</i>	
<i>Staphylococcus epidermidis</i>	
<b>Other</b>	
<b>Streptococci group B</b>	
<b>Gram positive rods</b>	
<i>Clostridium perfringens</i>	
<i>Corynebacterium urealyticum</i>	
<i>Lactobacillus</i> spp.	
<b>Acid-fast bacteria</b>	
<i>Mycobacterium tuberculosis</i>	

FIG. 12A

Fungi	Candida spp.
	Candida albicans
	Candida parapsilosis
	Candida pseudotropicalis
	Candida tropicalis
	Candida glabrata
	Candida krusei
	Candida norvegensis
	Candida guilliermondii
	Candida lusitanae
	Non-candida spp.
	Actinomyces spp.
	Aspergillus spp.
Parasites	Blastomyces dermatitidis
	Cryptococcus neoformans
Viral	Chlamydia trachomatis
	Schistosoma haematobium
	Adenovirus

FIG. 12B

TABLE 6 (Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
1	No objective evidence of active urinary tract infection. None of the indications to treat asymptomatic infection are present.	Infection asymptomatic and culture is negative, then state "Antibiotic therapy not recommended on the basis of the available information"
2	No objective evidence of active urinary tract infection. None of the indications to treat asymptomatic infection are present.	Infection asymptomatic "and organism uncertain" and none of the factors listed in table "asymptomatic" present then state "Antibiotic therapy not recommended on the basis of the available information."
3	More than 3 positive organisms in a urine culture typically indicates contamination.	If >3 organisms identified, then state "Recommend repeat culture"
4	Antibiotic therapy highly active against both gram negative rods and gram positive cocci; recommended because of risk factors and upper tract infection.	(Organism uncertain or urine collection none) and upper tract infection and (obstruction or abnormal anatomy or recent urologic surgery), then recommend (vancomycin and ciprofloxacin IV), piperacillin/tazobactam, (vancomycin and gentamicin)
5	Antibiotic therapy highly active against both gram negative rods and gram positive cocci; recommended because of risk factors and upper tract infection.	(Organism uncertain or urine collection none) and upper tract infection and renal transplant, recommend piperacillin/tazobactam, (vancomycin and ciprofloxacin IV), (vancomycin and gentamicin)
6	Sexually active young adults between the ages of >17 and age <30 with symptomatic sterile pyuria are at increased risk for <i>Chlamydia trachomatis</i> urethritis. Recommended antibiotic is active against suspected organisms associated with this clinical syndrome.	Organism uncertain and culture is negative and urine collection is clean catch and therapy is outpatient and infection is lower tract and age >17 and age <30, then recommend doxycycline PO, azithromycin PO, FQ PO

TABLE 6 (Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
7	The recommended antibiotic is active against organisms commonly associated with lower tract urinary infections. FQ is recommended first line therapy in the absence of contraindications when the prevalence of E.coli resistance to TMP/SMX is at least 20%	(Organism uncertain or urine collection none) and lower tract/asymptomatic, then recommend FQ PO, sulfamethoxazole-trimethoprim PO, nitrofurantoin PO, amoxicillin/clavulanate PO, cephalexin PO
8	The recommended oral antibiotic therapy is active against organisms commonly associated with urinary tract infection and is superior to oral beta-lactam antibiotics for treatment of upper tract infection.	(Organism uncertain or urine collection none) and upper tract and outpatient, then recommend FQ PO, sulfamethoxazole-trimethoprim PO, amoxicillin-clavulanate PO, cephalexin PO
9	The recommended intravenous antibiotic therapy is highly active against organisms commonly associated with upper tract urinary infection.	(Organism uncertain or urine collection none) and upper tract and inpatient, then recommend <u>FQ IV</u> , 3 <sup>rd</sup> gen ceph, sulfamethoxazole-trimethoprim IV, gentamicin IV + vancomycin IV)
10	The recommended antibiotic therapy is active against Pseudomonas aeruginosa and gram positive organisms.	Organism pseudomonas aeruginosa and (GPC or GPR) and upper tract, then recommend piperacillin-tazobactam IV, imipenem IV, (vancomycin IV + ciprofloxacin IV), consult
11	The recommended antibiotic therapy is active against susceptible Pseudomonas aeruginosa and gram positive organisms. If unable to take oral ciprofloxacin, then intravenous therapy recommended.	Organism pseudomonas aeruginosa and (GPC or GPR) and lower tract, then recommend ciprofloxacin PO, ciprofloxacin PO + amoxicillin/clavulanate PO

TABLE 6 (Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
18	The recommended antibiotic therapy is active against gram negative rods. FQ is recommended first line therapy in the absence of contraindications when the prevalence of E.coli resistance to TMP/SMX is at least 20%.	Organism GNR and susceptibility not known and lower tract/asymptomatic then recommend FQ PO, sulfamethoxazole-trimethoprim PO, nitrofurantoin PO, amoxicillin/clavulanate PO, cephalexin PO
19	TMP/SMX is recommended first line therapy when the gram negative rod is known to be susceptible. Alternative antibiotic agents are recommended when the organism is resistant to TMP/SMX or a contraindication to TMP/SMX is present.	Organism GNR and susceptibility results known and lower tract/asymptomatic, then recommend sulfamethoxazole-trimethoprim PO, FQ PO, cephalexin PO, nitrofurantoin PO
20	The recommended antibiotic therapy is active against susceptible enterococci and staphylococci.	Organism enterococcus and upper tract and (Staphylococcus aureus or Staph coagulase-negative) and susceptibility not known, then recommend vancomycin IV, ampicillin-sulbactam IV, consult
21	The recommended antibiotic therapy is active against enterococci and staphylococci. Ampicillin/sulbactam is preferred to vancomycin for treatment of beta-lactam susceptible staphylococci.	Organism enterococcus and upper tract and (Staphylococcus aureus or Staph coagulase-negative) and susceptibility known, then recommend ampicillin-sulbactam IV, vancomycin IV, quinupristin IV *, consult *
22	The recommended antibiotic therapy is active against susceptible enterococci and staphylococci.	Organism enterococcus and lower tract and (Staphylococcus aureus or Staph coagulase-negative), then recommend amoxicillin-clavulanate PO, FQ PO, doxycycline PO, vancomycin PO

TABLE 6 (Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
23	The recommended antibiotic therapy is active against <i>Staphylococcus aureus</i> . Vancomycin is first line therapy for inpatient upper tract infection pending susceptibility.	Organism <i>Staphylococcus aureus</i> and inpatient and upper tract infection and susceptibility not known, then recommend vancomycin IV, Nafcillin IV, Cefazolin IV, consult.
24	The recommended antibiotic therapy is active against <i>Staphylococcus aureus</i> . Nafcillin is preferred to vancomycin for susceptible organisms.	Organism <i>Staphylococcus aureus</i> and inpatient and upper tract infection and susceptibility known, then recommend nafcillin IV, cefazolin IV, vancomycin IV, quinupristin IV *, Consult *.
25	The recommended antibiotic therapy is active against susceptible <i>Staphylococcus aureus</i> .	Organism <i>Staphylococcus aureus</i> and outpatient and lower tract/asymptomatic infection then recommend, dicloxacillin PO, cephalexin PO FQ PO, sulfamethoxazole-trimethoprim PO.
26	The recommended intravenous antibiotic therapy is active against susceptible <i>Staphylococcus aureus</i> .	Organism <i>Staphylococcus aureus</i> and outpatient and upper tract, then recommend nafcillin IV, cefazolin IV, vancomycin IV, quinupristin IV *, consult *.
27	The recommended therapy is active against <i>Staphylococcus saprophyticus</i> .	(Organism <i>Staphylococcus saprophyticus</i> or (organism <i>Staph</i> coagulase-negative and female and age >15 and <50 years and no urinary obstruction and no abnormal anatomy and urine is clean catch)) and ((inpatient and lower tract/asymptomatic) or (outpatient)), then recommend sulfamethoxazole-trimethoprim PO, cephalexin PO, FQ PO.
28	The recommended intravenous therapy is active against <i>Staphylococcus saprophyticus</i> .	(Organism <i>Staphylococcus saprophyticus</i> or (organism <i>Staph</i> Coagulase-negative and female and age >15 and <50 years and no urinary obstruction and no abnormal anatomy and urine is clean catch)) and inpatient and upper tract, then recommend cefazolin IV,

TABLE 6 (Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
29	The recommended therapy is active against <i>Staphylococcus</i> coagulase negative. This organism is usually resistant to beta-lactam antibiotics.	Organism <i>Staph</i> coagulase-negative and susceptibility not known, then recommend vancomycin IV, consult.
30	The recommended intravenous antibiotic therapy is active against susceptible coagulase negative staphylococci. Cefazolin is preferred to vancomycin for susceptible organisms.	Organism <i>Staph</i> coagulase-negative and susceptibility known and upper tract, then recommend cefazolin IV, vancomycin IV, consult.
31	The recommended antibiotic therapy is active against susceptible coagulase negative staphylococci.	Organism <i>Staph</i> coagulase-negative and susceptibility known and lower tract/asymptomatic, then recommend dicloxacillin PO, sulfamethoxazole-trimethoprim PO, doxycycline PO, vancomycin PO, consult.
32	The recommended intravenous antibiotic therapy is active against susceptible enterococci.	Organism enterococcus and upper tract infection, then recommend ampicillin IV, vancomycin IV, consult.
33	The recommended antibiotic therapy is active against susceptible enterococci.	Organism enterococcus and lower tract/asymptomatic infection, then recommend amoxicillin PO, nitrofurantoin PO, doxycycline PO.
34	The recommended antibiotic therapy is active against group B streptococci.	Organism <i>Streptococci</i> Group B and upper tract, then recommend ampicillin IV, cefazolin IV, vancomycin IV.

TABLE 6 (Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
35	The recommended antibiotic therapy is active against group B streptococci.	Organism Streptococci Group B and lower tract/asymptomatic, then recommend amoxicillin PO, cephalexin PO, sulfamethoxazole-trimethoprim PO.
36	The recommended antibiotic therapy is active against <i>Corynebacterium urealyticum</i> .	Organism <i>Corynebacterium</i> and susceptibility not known, then recommend vancomycin IV.
37	The recommended antibiotic therapy is active against <i>Corynebacterium urealyticum</i> . Ampicillin is preferred to vancomycin for susceptible organisms.	Organism <i>Corynebacterium</i> and susceptibility known, then recommend ampicillin IV, vancomycin IV, consult.
38	The recommended antibiotic therapy is active against <i>Lactobacillus</i> .	Organism <i>Lactobacillus</i> and lower tract, then recommend amoxicillin-PO, clarithromycin PO, clindamycin PO.
39	The recommended antibiotic therapy is active against <i>Lactobacillus</i> .	Organism <i>Lactobacillus</i> and upper tract, then recommend ampicillin IV, clindamycin IV, erythromycin IV.
40	The recommended antibiotic therapy is active against <i>Staphylococcus saprophyticus</i> which is the likely organism.	Organism GPC not further identified and female and age >15 and <50 years and clean catch and outpatient, then recommend sulfamethoxazole-trimethoprim PO, amoxicillin-clavulanate PO.
41	The recommended intravenous antibiotic therapy is active against gram positive organisms.	Organism one or more GPC or GPR not further identified and upper tract infection, then recommend ampicillin-sulbactam IV, vancomycin IV.
42	The recommended antibiotic therapy is active against gram positive organisms.	Organism one or more GPC or GPR not further identified and lower tract/asymptomatic infection, then recommend amoxicillin-clavulanate PO, nitrofurantoin PO, doxycycline PO

TABLE 7 (Candida and Miscellaneous Organism Rules (Optionally Sequential))

- |   |   |   |
|---|---|---|
| 1 | Antibiotic therapy highly active against both gram negative rods and gram positive cocci; recommended because of risk factors and upper tract infection.  | Organism chlamydia, then recommend doxycycline PO, azithromycin PO, amoxicillin PO.   |
| 2 | The recommended antibiotic therapy is active against <i>Staphylococcus aureus</i> . Vancomycin is first line therapy for inpatient upper tract infection pending susceptibility.                        | Organism mycobacterium, then recommend consult  |
| 3 | The recommended antibiotic therapy is active against susceptible <i>Pseudomonas aeruginosa</i> and gram positive organisms. If unable to take oral ciprofloxacin, then intravenous therapy recommended. | Organism <i>Candida</i> and lower tract and not Foley catheter, then recommend fluconazole PO, amphotericin B IV, consult *.    |
| 4 | The recommended antibiotic therapy is active against susceptible <i>Pseudomonas aeruginosa</i> and gram positive organisms.   | Organism <i>Candida</i> and lower tract and Foley catheter, then recommend fluconazole PO, amphotericin B IV, bladder washing * |
| 5 | The recommended antibiotic therapy is active against group B streptococci.  | Organism <i>Candida</i> and upper tract, then recommend amphotericin B IV, fluconazole IV, consult.                             |

FIG. 14

TABLE 8 (Duration Rules (Optionally Sequential))

- |   |          |  |
|---|----------|--|
| 1 | 14 days. | Infection upper tract or early recurrence or suprapubic catheter   |
| 2 | 1 day.   | Organism is chlamydia and (pregnant or age <8) then recommend 1 day duration.  |
| 3 | 3 days.  | Infection lower tract and outpatient and no duration factors (table: "duration factors") present and recommended therapy is (FQ or TMP/SMX) and ((urine collection clean catch and is not culture negative and organism is not GPC, GPR, chlamydia, <i>Pseudomonas aeruginosa</i> , <i>Candida</i> ) or (urine collection method is "none collected")) |
| 4 | 7 days   | Recommend 7 days duration  |

FIG. 15

TABLE 9 (One or more optional Caveats)

1	Remove Foley catheter if possible.	Urine collection method Foley catheter
2	If catheter not removed, treat for 14 days.	Urine collection method Foley catheter and (lower tract infection or asymptomatic)
3	If clinical response is satisfactory after 2-3 days and GI absorption is adequate, therapy may be switched to oral agent based on organism identification and susceptibility.	Inpatients and upper tract infection
4	Collect urine specimen.	Urine collection none (and infection is upper tract or any duration factors present)
5	Collect urine specimen if clinical response unsatisfactory.	Urine collection none (and infection is not upper tract and no duration factors present)
6	Assumes urine microscopic exam shows WBCs. If sexually active, recommend evaluation for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> .	Organism uncertain and culture is negative and urine collection is clean catch and therapy is outpatient and infection is lower tract
7	Sexual partners should be referred for evaluation and treatment.	Organism chlamydia
8	This organism is associated with encrusted cystitis and pyelitis.	Organism corynebacterium
9	Confirm isolated enterococcus is sensitive to ampicillin.	Organism Enterococcus is resistant to vancomycin and is not resistant to ampicillin
10	Recommend repeat culture prior to starting antibiotics.	Three organisms identified

FIG. 16

TABLE 10 (Mitigating Factors)

#	Factor
1	If pregnant, query "Near term?"
2	If penicillin allergy, query "Was penicillin allergy immediate-type"

FIG. 17

TABLE 11 (Sequentual Mitigating Factors)

#	Rule
1	If not upper tract and not ((suprapubic or nephrostomy) and lower tract), then query "Early relapse or recurrence?" and "Urinary obstruction or abnormal urologic anatomy?"
2	If female and not pregnant and clean catch and lower tract and age 15-50 and (organism uncertain or GNR not identified to species or E. coli), then query duration factors
3	If organism Staph coagulase negative or (organism uncertain and upper tract), then query urinary obstruction, abnormal urologic anatomy, recent urologic surgery
4	If asymptomatic and not pregnant and (organism not chlamydia or Salmonella) and age > 3, then query "Early post-renal transplant period?" and "Urinary obstruction or recent/planned urologic surgery?"

FIG. 18

TABLE 12 (Contraindications)

Medication	Contraindication
Penicillin	Penicillin allergy Imipenem allergy Cephalosporin allergy Penicillin resistance Cephalosporin resistance
Nafcilling, Dicloxacillin and Oxacillin	Penicillin allergy Imipenem allergy Oxacillin resistance
TMP/SMX	TMP/SMX or Sulfa allergy Nursing female Pregnant female near term TMP/SMX resistance
Cephalosporin	Immediate penicillin allergy Cephalosporin allergy Cephalosporin resistance Oxacillin resistance
Imipenem	Penicillin allergy Imipenem allergy Imipenem resistance History of seizure activity
Tetracyclines	Tetracyclines allergy Tetracyclines resistance Pregnancy Nursing Age < 8 years
FQ	Pregnancy Nursing Age < 18 years FQ resistance FQ allergy
Erythromycin estolate	Pregnancy

FIG. 19

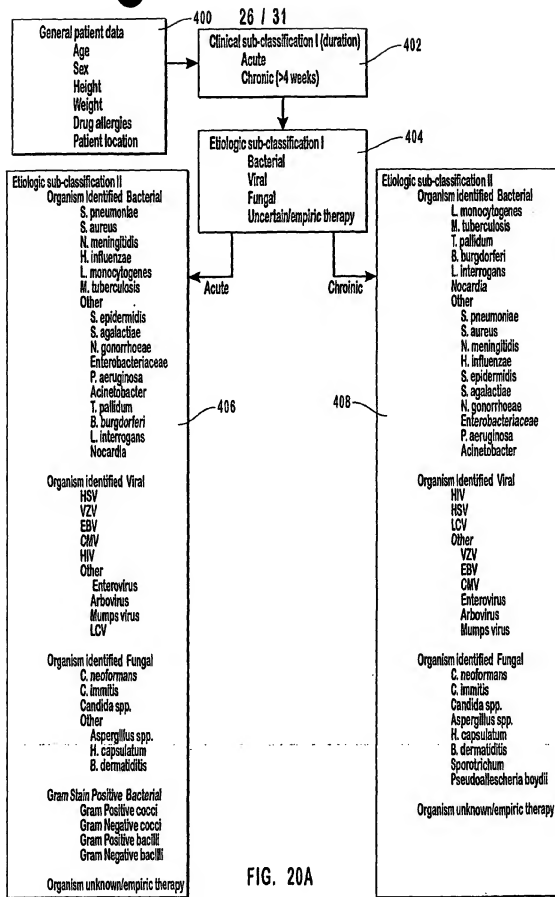


FIG. 20A

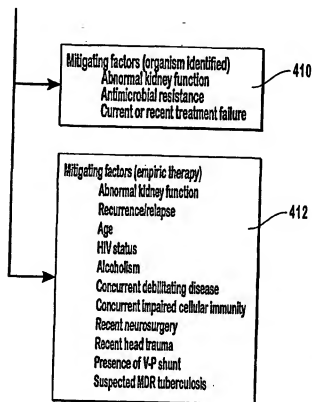


FIG. 20B

TABLE 13 (Meningitis Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
1	Broad empiric coverage which accounts for <i>Listeria</i> and gram-negative rods, as well as common gram-positive and gram-negative cocci (including DRSP)	If organism uncertain and patient has depressed cellular immunity OR age 1 month to 3 months), then: (3 <sup>rd</sup> gen ceph + ampicillin + vancomycin), (3 <sup>rd</sup> gen ceph + vancomycin), meropenem, chloramphenicol
2	Broad empiric coverage for common organisms, with coverage for DRSP and gram-negatives	If organism uncertain and age > 3 months, then (Vanco + 3 <sup>rd</sup> gen ceph), Meropenem
3	Broad empiric coverage aimed toward Group B Strep, <i>E. coli</i> , and <i>Listeria</i>	If organism uncertain and AGE (preterm to 1 month) then: (Amp + Cefotax), (Amp + Gent)
4	Empiric coverage primarily against <i>S. pneumoniae</i> . Initial coverage with Vanco is preferred to cover for DRSP, as well as MRSA or MRSE if clinically appropriate.	If GRAM-STAIN GRAM-POS COCCI, then (3 <sup>rd</sup> Gen Ceph + Vanco), (Vanco + Rif), 3 <sup>rd</sup> Gen Ceph, chloramphenicol
5	Empiric therapy primarily for <i>N. meningitidis</i>	If GRAM-STAIN GRAM-NEG COCCI then: 3 <sup>rd</sup> Gen Ceph, Chloramphenicol
6	Empiric therapy primarily for <i>Listeria</i>	If GRAM-STAIN GRAM-POS BACILLI then: (Amp + Gent), TMP/SMX
7	Empiric therapy for gram-negative rods, with particular attention to <i>H. influenzae</i> , coliforms, and <i>P. aeruginosa</i>	If GRAM-STAIN GRAM-NEG BACILLI then: Meropenem, ceftazidime
8	Recommended therapy is active against methicillin-resistant <i>S. aureus</i> and <i>S. epidermidis</i> (MRSA, MRSE)	If (organism <i>S. aureus</i> or organism <i>Staphylococcus</i> coagulase negative) and oxacillin resistant, then (vancomycin + rifampin), vancomycin,

TABLE 13 (Meningitis Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
9	Recommended therapy is active against methicillin-sensitive <i>S. aureus</i> and <i>S. epidermidis</i>	If organism ( <i>S. aureus</i> or <i>Staphylococcus coagulase</i> negative) and oxacillin susceptible and CNS shunt present (?), then (nafcillin + rifampin), nafcillin, (vancomycin + rifampin), vancomycin (should CNS shunt be in #9?)
10	Recommended therapy is active against <i>S. aureus</i> and <i>S. epidermidis</i> . Vancomycin is preferred when the rate of methicillin resistance exceeds 10%	If (organism <i>S. aureus</i> or <i>Staphylococcus coagulase</i> negative) and susceptibility unknown, Vancomycin, nafcillin
11	Recommended therapy is active against <i>S. pneumoniae</i> sensitive to penicillin or 3 <sup>rd</sup> Gen Ceph	If organism <i>S. pneumoniae</i> (Pen MIC <0.1 or Ceftriaxone MIC ≤ 0.5 ug/ml), then 3 <sup>rd</sup> Gen Ceph, (Vanco + Rif)
12	Recommended therapy is active against <i>S. pneumoniae</i> which has intermediate resistance to 3 <sup>rd</sup> Gen Ceph. It is also recommended as empiric therapy for <i>S. pneumoniae</i> when susceptibility is not known.	If organism <i>S. pneumoniae</i> and (susceptibility unknown or Ceftriaxone MIC > 0.5 ug/ml) then: (3 <sup>rd</sup> Gen Ceph + Vanco), (Vanco + Rif), Chloramphenicol
13	Recommended therapy is active against <i>S. pneumoniae</i> resistant to penicillin and ceftriaxone. A 3 <sup>rd</sup> Gen Ceph is recommended as it may still provide some <i>in vivo</i> activity.	If organism <i>S. pneumoniae</i> and Ceftriaxone MIC ≥ 2 ug/ml then: (3 <sup>rd</sup> Gen Ceph + Vanco + Rif), (Vanco + Rif), Chloramphenicol
14	Recommended therapy is active against <i>S. agalactiae</i>	If organism <i>S. agalactiae</i> , then (Amp + Gent), (Ceftriax or Cefotax), Vanco
15	Recommended therapy is active against <i>N. meningitidis</i>	If organism <i>N. meningitidis</i> then: 3 <sup>rd</sup> gen ceph, Chloramphenicol

FIG. 21B

TABLE 13 (Meningitis Anti-bacterial Antibiotic Selection Rules and Statements)

#	Statement	Rule
16	Recommended therapy is active against <i>L. monocytogenes</i>	If organism <i>L. monocytogenes</i> then: (Amp + Gent), ampicillin, TMP/SMX
17	Recommended therapy is active against <i>H. influenzae</i>	If organism <i>H. influenzae</i> then: 3 <sup>rd</sup> gen ceph, chloramphenicol
18	Recommended therapy is active against gram-negative rods, with particular attention to <i>H. influenzae</i> , coliforms, and <i>P. aeruginosa</i>	If organism gram negative rod then: meropenem, intrathecal gentamicin
19	Recommended therapy is active against <i>P. acnes</i>	If organism is <i>Propionibacterium acnes</i> , then penicillin G, chloramphenicol

## FIG. 21C

TABLE 14 (Duration Rules)

- 1 If organism is gram negative rod or listeria then state "Recommended duration of antibiotic therapy is 3 weeks"
- 2 If organism is *H. influenzae* or *N. meningitidis*, state "Recommended duration of antibiotic therapy is 7 days"
- 3 If organism is *S. aureus* or Staphylococcus coagulase negative or *S. agalactiae*, state "Recommended duration is 14 - 21 days"
- 4 If organism is *S. pneumoniae*, state "Recommended duration is 10-14 days"

## FIG. 22

TABLE 15 (Mitigating Factor Rules)

- 1 If organism is uncertain, then query "Does patient have depressed cellular immunity (HIV infection, organ transplantation, chronic steroid use)?"
- 2 Query if CNS shunt present

FIG. 23

TABLE 16 (Caveats)

- 1 If CNS shunt present, then state "Removal of shunt probably necessary for cure"
- 2 State "Recommendations for treatment duration are general guidelines; treatment should be tailored to the individual's response"
- 3 In cases of proven or strongly suspected bacterial meningitis, dexamethasone should be given at the time of the first dose of antibiotic, particularly when there are signs of increased intracranial pressure.
- 4 If organism gram negative rod and not *H. influenzae*, then state "Intrathecal gentamicin may be considered in the event of poor clinical response to intravenous antibiotics"
- 5 If organism is *Listeria* or *S. agalactiae*, state "Gentamicin may be stopped after 5 to 7 days of therapy if the clinical response is adequate"

FIG. 24

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/17393

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G06F 17/60

US CL : 705/2

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/2,3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
West - USPatents and Derwent

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P ---	US 6,149,585 A (GRAY) 21 November 2000 (21.11.2000), Abstract, Figs. 2, 12, 13, 15-22, 35, cols. 2-3 lines 38-4, col. 3, lines 50-33, col. 4, lines 13-21 and 41-49, col. 5, lines 4-64, col. 7, lines 24-47, col. 9, lines 6-7, and 29-55, cols. 9-10, lines 56-17, cols. 10-11, lines 11-44.	1-9, 12-33, 35-36, 38-50, 52, 54-59, 61-86, 89-96, 98
Y,P	US 6,177,940 B1 (BOND, et al.) 23 January 2001 (23.01.2001), Fig. 5.	10-11, 51, 87-88
Y,P	US 5,301,105 A (CUMMINGS, JR.) 05 April 1994 (05.04.1994), Fig. 1, col. 4, lines 53-67, col. 5, lines 1-8, col. 11, lines 44-60, col. 13, lines 31-59.	87-88
Y	US 6,141,581 A (KRAFTSON, et al.) 21 November 2000 (21.11.2000), entire document.	49, 97
A		1-99

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

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"Z" document member of the same patent family

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